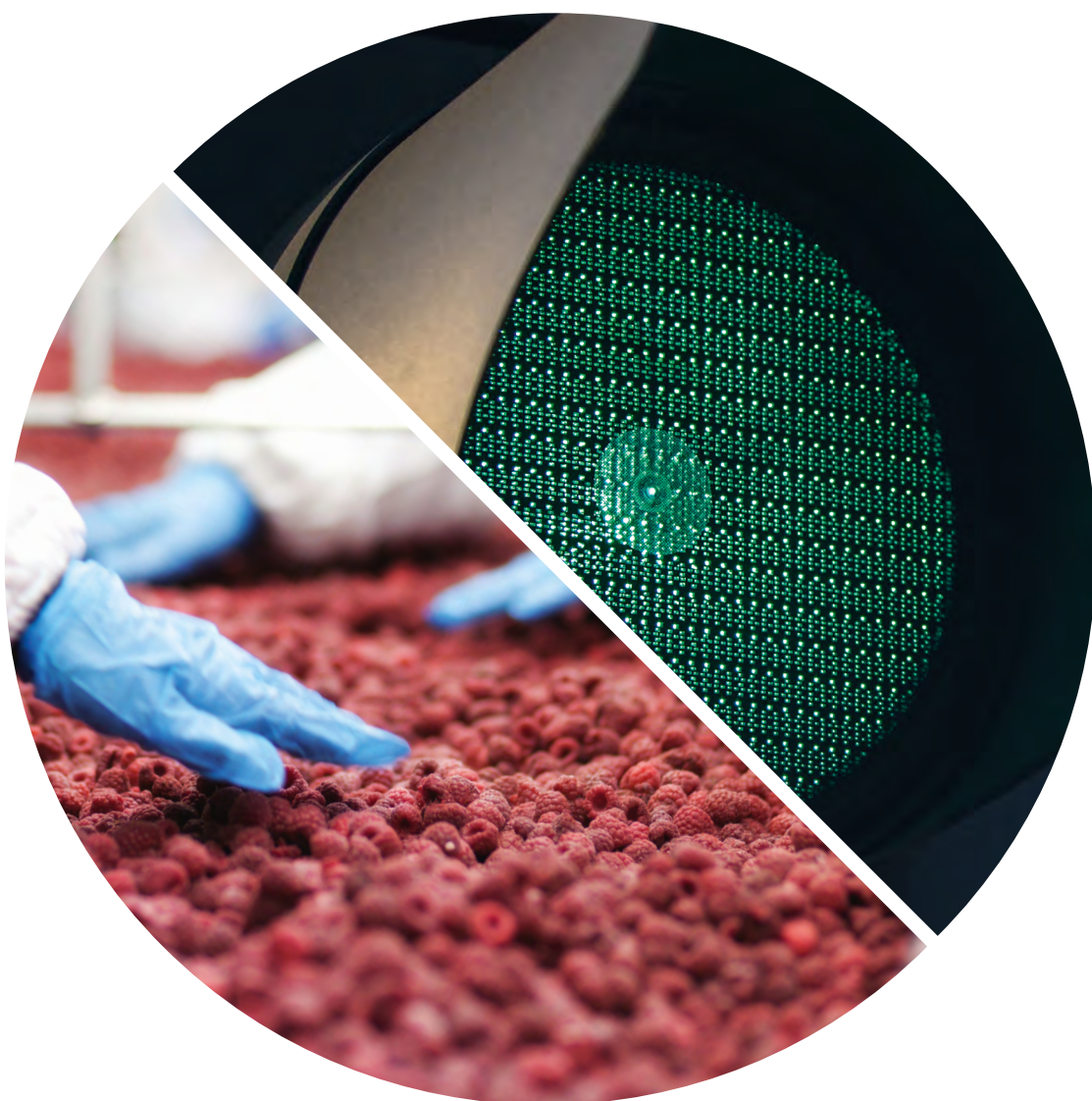


ISO 22000

Food Safety Management Systems

Your implementation guide



ISO 22000 Food safety management systems

The World Health Organization estimates that one in ten people fall ill and 420,000 die because of contaminated food every year.¹ ISO 22000:2018 works preventively to reduce this by helping food organizations implement food safety management systems that defend against the potential hazards and risks that lead to contamination. From listeria outbreaks to incorrect labelling, compromised food products can negatively impact customer and consumer confidence in your business and your brand.

Food safety hazards can occur at any stage in the food chain making adequate control throughout the food chain essential. By combining PDCA and risk-based thinking to manage business risk with HACCP to identify, prevent and control food safety hazards, ISO 22000 helps organizations to reduce exposure to risk and improve safety.

Certification to the standard provides additional benefits to organizations throughout the food chain:

- Improved control over food safety activities
- Customer, statutory and regulatory compliance
- Facilitated market growth
- Increased customer, stakeholder and consumer confidence in products
- Improved risk management
- Integration with other ISO management systems

Why was the standard revised?

The expectation to deliver safe, sustainable and socially responsible food has increased significantly for the food sector since the standard was first published in 2005. To help food sector organizations manage these challenges the standard has been updated to take them into account. Additionally, during the development process the standard also adopted Annex SL. The high level structure (HLS) was introduced to align the implementation process of ISO management systems so that it was easier to adopt multiple management systems within individual organizations.

What kind of businesses can benefit from the standard?

An ISO 22000 food safety management system (FSMS) can be implemented in small, medium and large-sized food organizations from all aspects of the food chain:

- Food and ingredient manufacturers
- Retailers
- Wholesalers
- Agricultural producers
- Transport, logistics and storage providers
- Packers
- Equipment and packaging manufacturers
- Caterers

¹ <http://www.who.int/en/news-room/fact-sheets/detail/food-safety>

How ISO 22000 works

One of the key differences between the 2005 and 2018 versions is how the prescriptive content is structured. Annex SL was developed by ISO as a framework for a generic management system. It's the framework for a generic management system and the blueprint for all new and revised management system standards going forward.

In addition to making ISO 22000 and the resulting FSMS easier to integrate with other ISO management systems, the new version of the standard is based on a process approach. By combining the Plan-Do-Check-Act cycle to manage business risk with HACCP to identify, prevent and control food safety hazards, ISO 22000 helps organizations to reduce exposure to risk and improve safety.

This combines both organizational and operational risk management into one management system. Organizationally, this approach provides the opportunity to consider all the different things that might impact your company, both good and bad. This allows you to prioritize the objectives of your FSMS so that it's implemented in a way that can accommodate the effects of these risks should they occur. On the operational side, risk-based thinking

and implementation is based on the principles of HACCP traditionally associated with food safety management. How they interrelate can be seen in the diagram below. Reproduced from ISO 22000:2018.

The potential benefits of combining risk-based thinking, PDCA and the process approach include:

- Focussing your FSMS and activities on higher-risk processes
- Understanding how processes within your organization are interdependent
- More effective use of resources
- Improved agility in meeting the requirements of new customers and/or meet new requirements established by existing customers

Contents

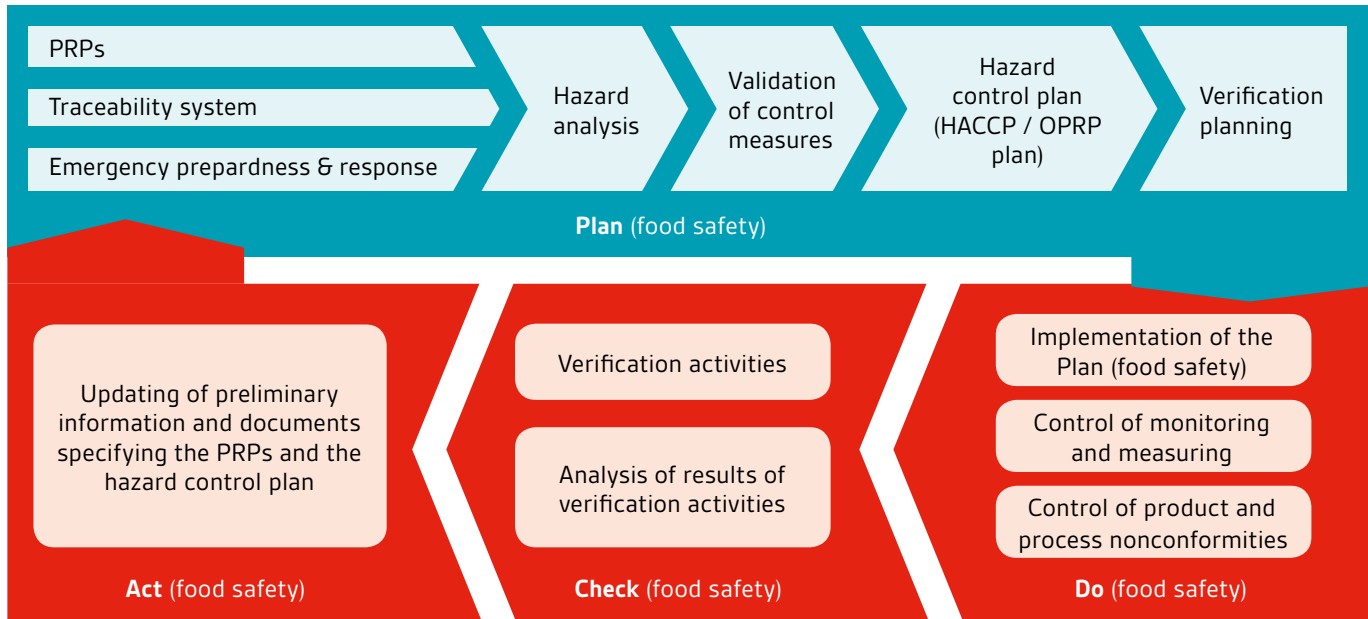
- How ISO 22000 works
- Core concepts
- Key requirements
- Top tips from our clients
- Your ISO 22000 journey
- BSI Training Academy
- BSI Business Improvement Software

Organizational planning and control



How ISO 22000 works

Operational planning and control



Some of the core concepts of ISO 22000 include:

| Concept | Comment |
|-------------------------------------|--|
| Context of the organization | The range of issues that can affect, positively or negatively, the way an organization manages its food safety responsibilities. |
| Issues | Issues can be internal or external, positive or negative and include a number of things that either affect or are affected by the organization. |
| Interested parties | Much more detail about considering stakeholder needs and expectations, then deciding whether to adopt any of them as compliance obligations. |
| Leadership | Requirements specific to top management; who are defined as a person or group of people who direct and control an organization at the highest level. |
| Risk and opportunities | Refined planning process replaces preventive action. Aspects and impacts now part of risk model. |
| Communication | There are explicit and more detailed requirements for both internal and external communications. |
| Nonconformity and corrective action | More detailed evaluation of both the nonconformities themselves and corrective actions required. |
| Performance evaluation | Covers the measurement of the FSMS to identify how operations could be improved or enhanced. |



Key requirements of ISO 22000

Clause 1: Scope

This clause details the scope of the international standard. This includes requirements about planning, implementation, maintaining and updating an FSMS as well as effective communications.

Clause 2: Normative references

There are no normative references within the standard. The clause is retained in order to maintain the same numbering scheme as all the other ISO management system standards.

Clause 3: Terms and definitions

Listed in alphabetical order, this section provides formal definitions of important terms used throughout the standard.

Clause 4: Context of the organization

This clause establishes the context of your FSMS and underpins the rest of standard. You will need to identify external and internal issues and the needs and expectations of your stakeholders and interested parties, as well as how value is delivered to them. It also partly addresses the concept of the creation of value.

In this case the term 'issue' covers not only problems or potential problems, but also important topics for the system to address, such as changing circumstances, legal requirements and other obligations.

This clause also includes determining the scope of the food safety management system. The scope is intended to clarify the boundaries to which the

system will apply. Additionally, Clause 4 requires you to establish, implement, maintain and continually improve the management system in accordance with the requirements of the standard.

Clause 5: Leadership

This clause is all about the role of "top management" which is the person or group of people who direct and control your organization at the highest level. The purpose is to demonstrate leadership and commitment by integrating the FSMS into the business' overall strategy.

Top management must demonstrate a greater involvement in the management system and need to establish the food safety policy, which can include commitments specific to your organization's context beyond those directly required.

There is also more focus on top management's commitment to continual improvement of the management system. Communication is key and top management have a responsibility to ensure its structure and detail is made available, communicated, maintained and understood by all parties.

Finally, top management need to assign relevant responsibilities and authorities, to a food safety team leader, as well support the people who are involved as the system is developed, implemented and as it evolves. Depending on the skillset of the chosen implementation, maintenance and improvement team(s), management also has make sure that all team members have the appropriate experience and/or receive training to successfully accomplish the tasks they are assigned.



Clause 6: Planning

This clause focuses on how an organization plans actions to address both the risks and opportunities identified in Clause 4. It focuses on the development and use of a planning process, rather than a procedure to address both a range of factors and the risk associated with such factors.

Consideration of risks needs to be proportionate to the potential impact they may have. Another key area of this clause is the need to establish measureable objectives and then communicate and monitor those objectives. Finally this clause states that the 'who, what, where and when' associated with achieving the objectives must be identified.

Clause 7: Support

This clause is all about the execution of the plans and processes that will enable your organization to successfully complete their FSMS responsibilities. This is a very powerful requirement covering all management system resource needs.

Organizations will need to determine the necessary competence of people doing work that, under

its control, affects the management system's performance, its ability to fulfil its obligations and ensure they receive the appropriate training.

In addition, organizations need to ensure that all people doing work under the organization's control are aware of the food safety policy, how their work may impact this and implications of not conforming to the FSMS. There are also the requirements for 'documented information' which relate to the creation, updating and control of specific data.

A corporate relationship management plan that captures this is also needed. It should define and link to your other management and operational processes and procedures.

Clause 8: Operation

This clause outlines the requirements your FSMS must meet for successful certification. Though they appear in a different clause number and sometimes in a different order, many of the concepts were included in ISO 22000:2005. Our ISO 22000 Mapping Guide can be downloaded from bsigroup.com if you'd like to better understand how the content has been restructured.



This clause covers:

- Operational planning and control
- Prerequisite programmes (PRPs)
- Traceability
- Emergency preparedness and response
- Hazard control
- PRP and hazard control maintenance
- Control of monitoring and measuring
- PRP and hazard control verification
- Control of product and process nonconformities

Clause 9: Performance evaluation

This is all about measuring and evaluating your food safety management system to ensure that it's effective and helps you to continually improve. You will need to consider what should be measured, the methods employed and when data should be analysed and reported on.

As a general recommendation, organizations should determine what information they need to evaluate performance and effectiveness.

Internal audits will need to be carried out, and there are certain "audit criteria" that are defined to ensure that the results of these audits are reported to relevant management. Finally, management reviews will need to be carried out and "documented information" must be kept as evidence.

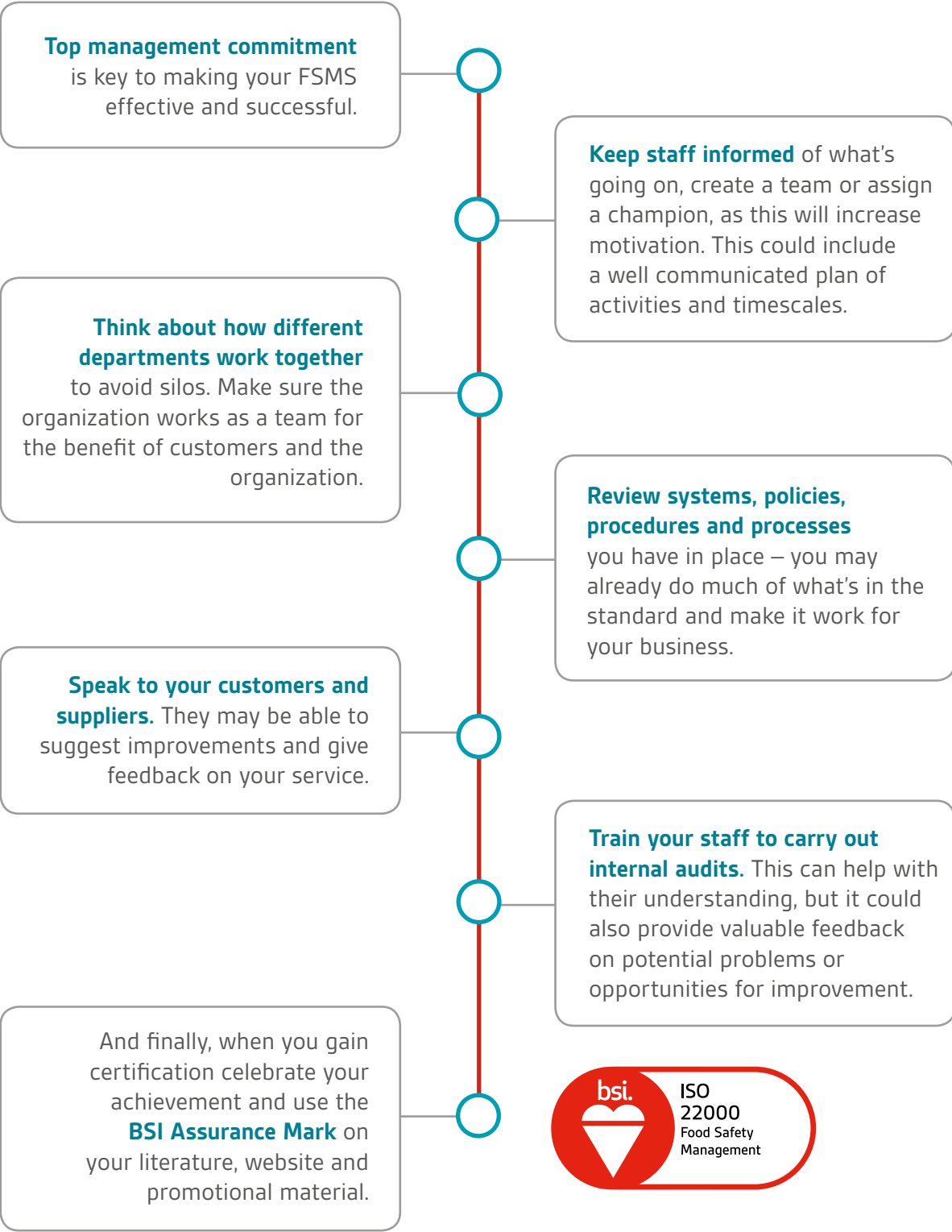
Clause 10: Improvement

This clause requires organizations to determine and identify opportunities for continual improvement of the management system. The requirement for continual improvement has been extended to ensure that its suitability and adequacy—as well as its effectiveness—are considered in light of enhanced food safety performance.

There are some actions that are required that cover handling of corrective actions. Organizations need to react to the nonconformities and take action AND they need to identify whether similar nonconformities exist or could potentially occur. This clause requires you to determine and identify opportunities for continual improvement of the FSMS.

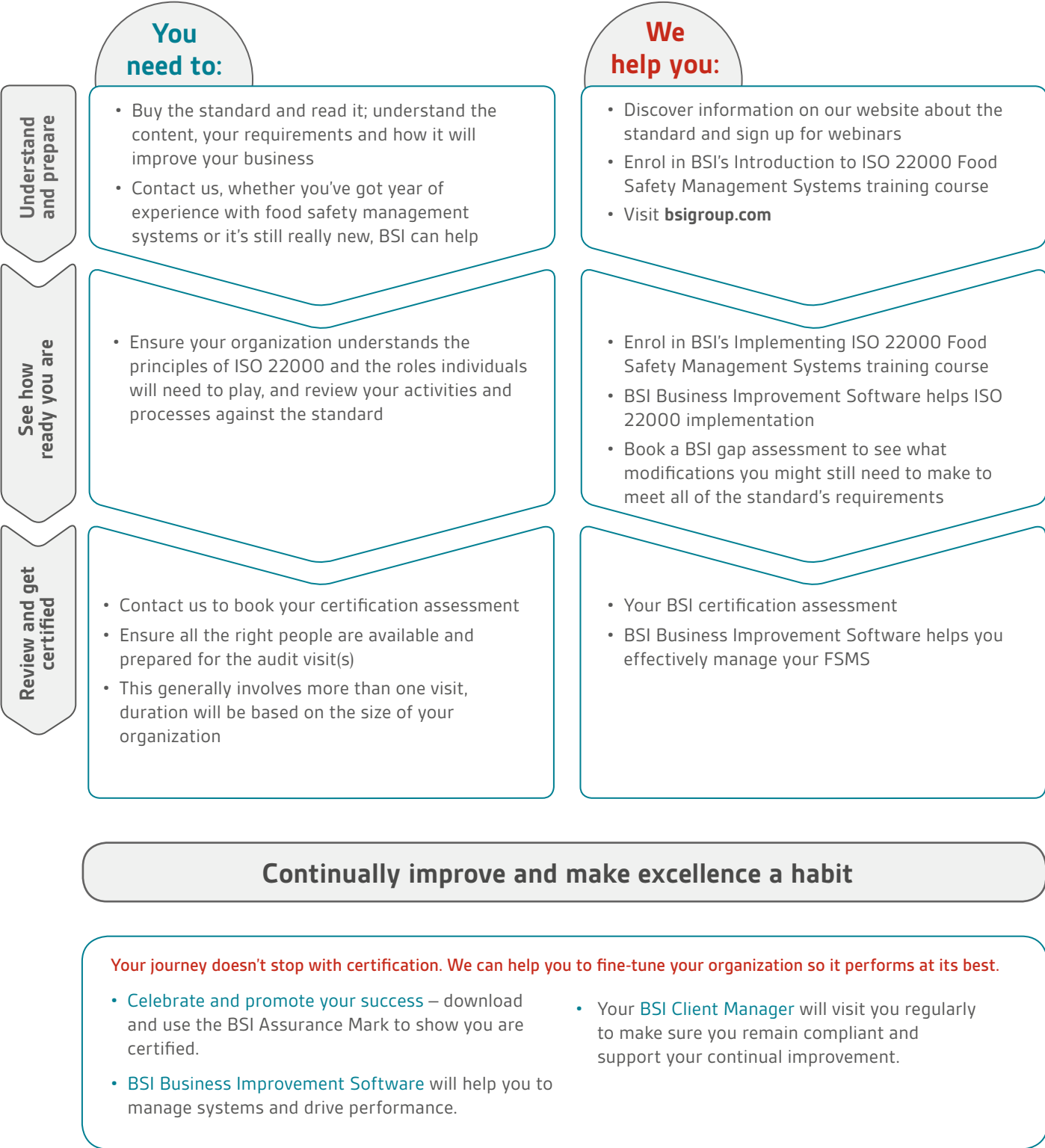
Top tips on making **ISO 22000** effective for you

Every year we have interactions with tens of thousands of clients. Here are their suggestions for maximizing your implementation and certification.



Your **ISO 22000** Journey

Whether you're new to management systems or looking to enhance your current system, we have the right resources and training courses to help you understand and implement ISO 22000. But our support doesn't stop there. We can help make sure your FSMS delivers the best for your business.



Train with BSI

BSI is a world leader in helping clients develop the knowledge and skills they need to embed excellence in their organizations. Whether your organization is going to certify or is simply looking to implement a management system for food safety, our training can make sure the people responsible for making things happen understand all the important and relevant details.

Using the latest research, our accelerated learning approach is proven to fast-track learning and improves knowledge retention. Our experienced tutors can help you get to grips with the matters that concern you and your organization directly, whether the course is delivered in-house or as part of a public course where other delegates can share their experience.

Our courses that can help you understand, implement and successfully certify to ISO 22000 include:

Transition-specific courses

These courses are designed for organizations already certified to ISO 22000:2005 who want to make their transition to the new standard as:

- ISO 22000:2018 Senior Management Briefing (half-day)
- ISO 22000:2018 Transition Briefing (one day)
- ISO 22000:2018 Transition Seminar (half-day)

General Courses

These courses are suitable for people who work for organizations that are new to ISO 22000 or are transitioning from the older version to ISO 22000:2015:

- ISO 22000:2018 Requirements (one day)
- ISO 22000:2018 Implementing (two days)
- ISO 22000:2018 Internal Auditing (two days)
- ISO 22000:2018 Lead Auditor (five days)

IRCA-certified ISO 22000:2018 courses:

- ISO 22000:2018 Auditor Transition (two days)
- ISO 22000:2018 Lead Auditor (five days)

Visit [bsigroup.com](https://www.bsigroup.com) to learn more about the availability and timing of our food safety-related training opportunities.

BSI Business Improvement Software

Accelerate implementation time and deliver continual improvements

The decision to implement the new ISO 22000 management system standard is a huge opportunity to drive business improvement; but initiating, implementing, and maintaining this can also be a challenge. Ensuring you get the most from your investment is a key driver to your future success. BSI Business Improvement Software provides a solution that can significantly reduce the cost and effort to an effective management system such as ISO 22000. It can be configured to the requirements of ISO 22000 and provide your organization with the tools necessary to manage essential elements of ISO 22000. The start of your ISO 22000 journey is an ideal time to implement BSI Business Improvement Software to support your management system.

It can help you to:

- Accelerate implementation time by up to 50%
- Effectively manage your document control
- Provide company-wide visibility on the status of your implementation of the standard so you know exactly where you are at any one time
- Easily and accurately input actions related to audits, incidents/events, risk and performance
- Have insight into trends that help you make business decisions early on and drive improvement through its customizable dashboards and reporting tools



Why BSI?

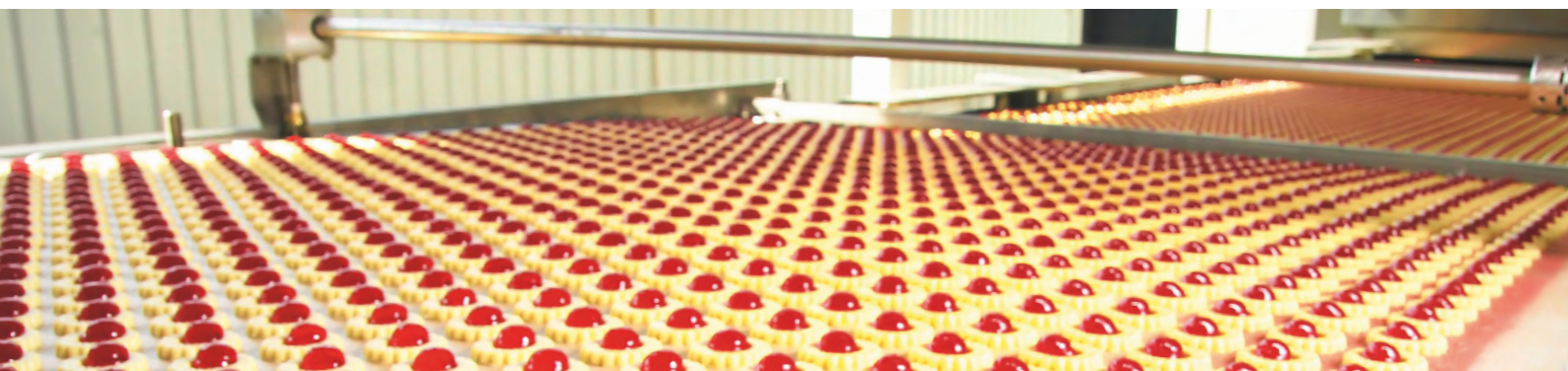


The food industry impacts every person on the planet. Though what the world's population may eat may differ depending on the geography, wealth, age, gender and availability of goods, no other sector plays such a vital role in all of our day-to-day lives and culture. Economically, food represents 10% of Global GDP (valued at US\$48 trillion by the World Bank).

But the food sector also faces significant challenges. Each year, food-borne illness makes one in ten people ill and is the cause of death for millions around the world. Population growth projections and an increasing middle class suggest that the demand for food will increase 70% by 2050. And, consumers are increasingly conscious about what goes into their food, how it's made, its impact on ecosystems and where it comes from.

BSI believes the world deserves food that is safe, sustainable and socially responsible. We support the food sector by developing and publishing standards of best practice, supply chain solutions as well as training and certification to not only the most popular food safety standards, but other business improvement standards that work together to make organizations more resilient.

Working in 172 countries, we pride ourselves on the expertise, integrity and professionalism of our people. Our mission is to help our 80,000 clients, ranging from high-profile global brands to small local companies, survive and prosper in today's world.



Our products and services

Knowledge

The core of our business centres on the knowledge that we create and impart to our clients. In the standards arena we continue to build our reputation as an expert body, bringing together experts from industry to shape standards at local, regional and international levels.

Assurance

Independent assessment of the conformity of a process or product to a particular standard ensures that our clients perform to a high level of excellence. We train our clients in world-class implementation and auditing techniques to ensure they maximize the benefits of standards.

Compliance

To experience real, long-term benefits, our clients need to ensure ongoing compliance to a regulation, market need or standard so that it becomes an embedded habit. We provide a range of services and differentiated management tools which help facilitate this process.



For more information on
ISO 22000:2018
visit **bsigroup.com** or email
bsi.me@bsigroup.com