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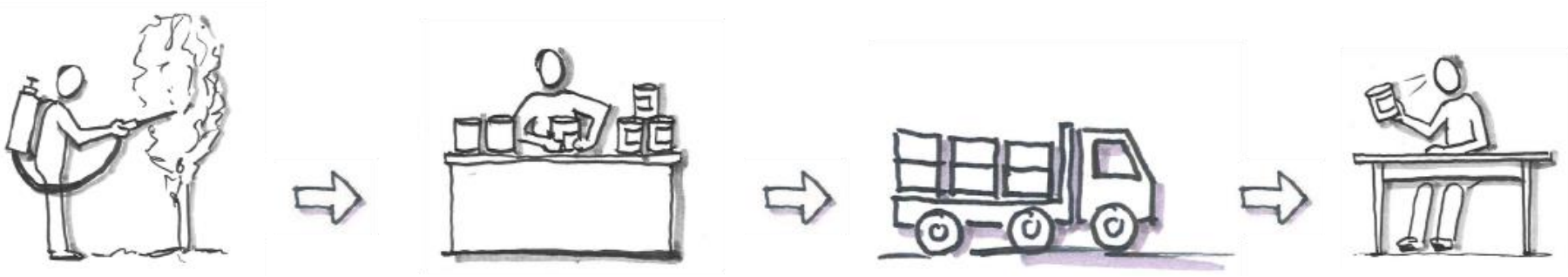
# Food Safety Management Systems (FSMS)



# How to use the IPD Guide on Food Safety Management Systems (FSMS)

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+ This guide gives basic information for companies that want to implement a **Food Safety Management Systems (FSMS)**. It is not comprehensive and should not be used as a guide to implementation.

+ It also includes information to support companies better understand the FSMS certification process.

**In this guide, you will find*:**

- ✓ What is FSMS
- ✓ History of FSMS and basic components
- ✓ Why should I apply FSMS
- ✓ Supportive Technical Standards
- ✓ Certification schemes
- ✓ Certification processes
- ✓ Overview of different standards

*For a detailed introduction to food safety issues see: *IPD guide on HACCP*

# What is a Food Safety Management System (FSMS)?

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The term is derived from the title of the international standard ISO 22000:

**"Food Safety Management Systems —**
**Requirements for any organization in the food chain"**

ISO 22000 is a standard published by the International Organization for Standardization (ISO). The standard provides a framework for effectively managing responsibilities of companies in the food value chain to assure customers and consumers of safe food.

There are a number of other standards based on the principles of FSMS. It is also possible to apply FSMS without certification.

International recognized certifications are based on international recognized standards.

# Who can apply FSMS?

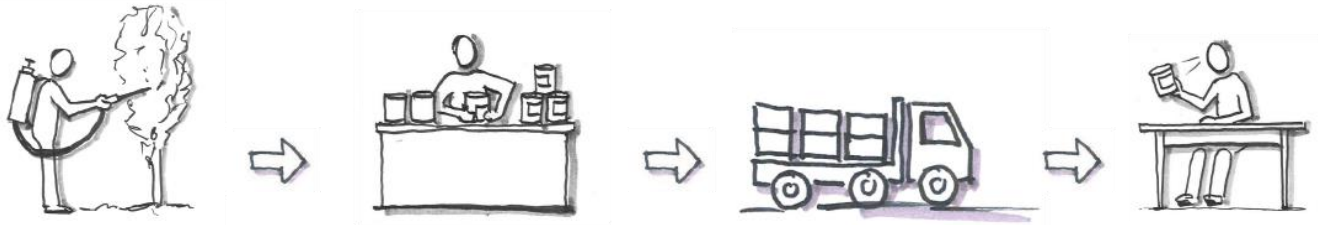
Everyone directly or indirectly involved in the food chain from primary production to final consumption can apply it. The application should be guided by scientific evidence of risks to human health.

**Directly involved**

+ Farmers
+ Food producers
+ Food retailers
+ Food service providers
+ Food manufactures
+ Cleaning and sanitation services
+ Food transporters
+ Food storage and distribution

**Indirectly involved**

+ Producers of ingredients
+ Animal food producers (pet food)
+ Feed producers ex. dairy, poultry etc.
+ Manufactures of food packaging material
+ Manufactures of food contact surfaces



# Why should my company apply FSMS?

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+ There are some strong reasons why producers and companies should take on the implementation of a food safety system:

- ✓ Facilitates international trade due to **increased confidence** in the supply chain!
- ✓ Employs a process based approach to foods safety hazards **consistent with operations**
- ✓ Is based on an international standard; hence, its certification has **global acceptance**
- ✓ Is **applicable to any organization** in the food chain regardless of size, product or service including less developed companies
- ✓ Incorporates the Plan – Do – Check and Act cycle (PDCA) for better **management**
- ✓ Employs the **risk based thinking** and thus **focuses on significant** hazards for better resource utilization
- ✓ Promotes a **common language** within the organization through use of procedures
- ✓ Improves **communication** across the supply chain and increases **transparency**

# 7 Principles of management of food safety

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1. **Customer focus -** Think about the customers needs and well being.
2. **Leadership -** Commitment of the Top Management is essential to drive food safety.
3. **Engagement of the people -** Competent company staff contribute to food safety. Through training and awareness they are empowered to act and give feedback.
4. **Process approach -** The activities of an organization are interlinked. The outputs of one process may have an impact on the end product, they should be viewed as a whole system and not independent parts.
5. **Improvement -** Company's sustainability is achieved by making it a permanent objective to improve e.g. processes, products, infrastructure, people etc.
6. **Evidence based decision making -** Records of all activities and results achieved need to be maintained. Objective decisions are made based on results of analyzed records.
7. **Relationship management -** Identify significant stakeholders e.g. suppliers and seek to build a relationship by mutually understanding each other.

# Key Elements of FSMS

1. **Interactive communication -** Communication with interested parties contributes to better understanding of food safety issues for efficient controls.

2. **System management -** The food chain is a whole system from farm to fork and a good understanding of it as a system contributes to better management.

3. **Prerequisite programs -** These are basic conditions that need to be in place within the organization for a FSMS to succeed. These conditions differ depending on which segment of the food chain one is in. Farm level - Good Agricultural Practice (GAP); Manufacturing - Good Hygiene Practice (GHP), Good Manufacturing Practice (GMP); Animal production- Good Veterinary Practice (GVP)

4. **HACCP principles* (H**azard **A**nalysi**s and C**ritical **C**ontrol **P**oints) application of risk based approach in food process operations, to ensure effective control of hazards.

* To learn about the HACCP principles see: *IPD guide on HACCP*

# Implementing FSMS using the PDCA cycle

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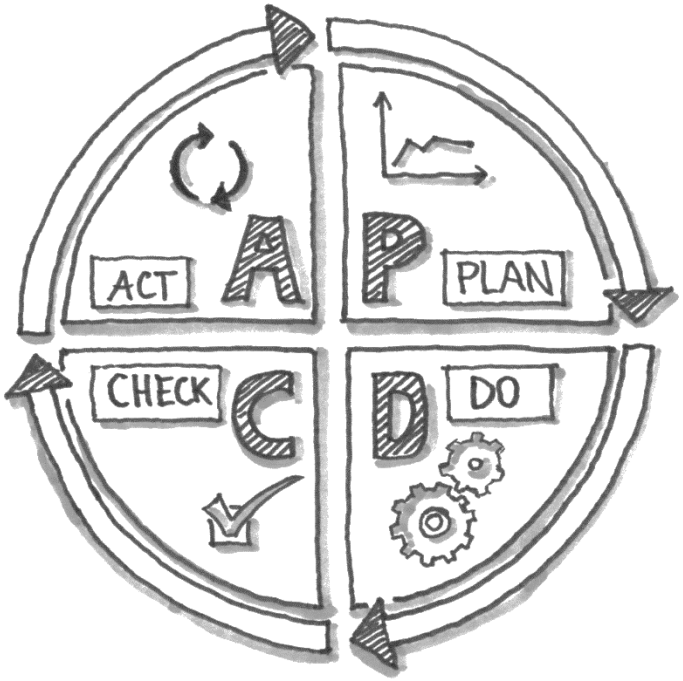
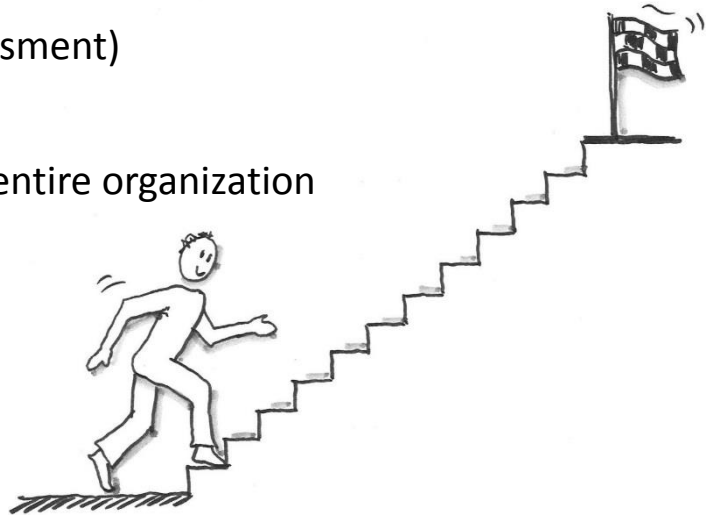
- **Plan:** Determine the goals that the company needs to achieve. Determine the processes, determine the resources required, and identify factors that can prevent or accelerate the achievement of the goals
- **Do:** Implement the plan, and keep records of observations and activities
- **Check:** Monitor, inspect, conduct tests, audits and analyze the records for all activities, process and products as applicable
- **Act:** Take action to improve the process, the product, the people, the infrastructure etc.



# 13 Step guide to implementing FSMS

1. Decision by top management to implement FSMS and whether/which certification is aimed for
2. Train key staff on the requirements of the applicable standard
3. Nominate the core team/Food Safety Team (FST)
4. Conduct a gap analysis based on the requirements of the standard, determine the resources
5. Close the prerequisite programs (PRPs) gaps. Apply the supportive technical standard ISO/TS*
6. Conduct an organizational risk assessment
7. Conduct a hazard assessment (operational risks assessment)
8. Document the food safety system
9. Train and raise awareness for implementation in the entire organization
10. Conduct an internal audit
11. Undertake corrective action
12. Conduct a management review and improve
13. Apply for certification (optional)



* See page 14 & 25

# Step 1: Decision by top management to implement FSMS

- Understand the organization's role in the food value chain and factors that influence it. e.g. national or foreign laws, availability of raw material, required versus available infrastructure.
- Understand the needs and expectations of all interested parties. Interested parties are all those who are likely to affect or be affected by the operations of the company e.g. government, consumers, customers, employees, suppliers.
- Define the boundaries of operation for the company. This may include the products, processes and production sites.
- Have a statement of commitment on food safety and communicate it to relevant stakeholders. This should then be implemented through fulfilling the requirements of the standards.
- Assign roles to ensure that the food safety requirements are implemented.
- Decide whether/which certification is aimed for.

# Step 2: Conduct training to key staff

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- Staff need relevant training based on the work assigned and their role within the organization. Trained staff feel empowered, and this is an extra advantage to the company

- Training may include:
  - The objectives of the company and their related tasks
  - The policy
  - How to perform their task and the impact of failure to do so
  - Awareness of FSMS and implications of not conforming to the requirements
  - Requirements of the standards
  - How to monitor and keep records

# Step 3: Nomination of the food safety team (FST)

- Appoint a food safety team with a team leader. The team should be multidisciplinary:
  - Food technologist
  - Microbiologist
  - Supervisors of the quality assurance, engineering, production and maintenance functions etc.
- If the team members require additional training, this should be arranged by the team leader.
- You may also engage a food safety consultant to support your team, but in no way should responsibilities be completely shifted from team to consultant.

# Step 4: Conduct a gap analysis

The food safety team and/or an external consultant/expert

- Prepares a checklist of all requirements based on the applicable standard.
- Reviews what is already existing within the company.
- Determines what is missing.
- Determines what is existing but inadequate, these could be:
  - Infrastructure
  - Records
  - Controls
  - Awareness
  - Equipment
  - Procedures
- Discusses the gaps with top management and prepare a plan to meet the gaps.

# Step 5: Close the prerequisites program gaps

- Prerequisites set out the necessary hygiene conditions for producing food which is safe and suitable for consumption.
- Depending on the segment of the food value chain the organization is in, it shall choose and apply the relevant prerequisite program.
- There are currently 6 published ISO standards on prerequisite programs for food safety management (that are applicable for all standards named in this guide):
  - ISO/TS 22002 - 1 Food manufacturing
  - ISO/TS 22002 - 2 Catering
  - ISO/TS 22002 - 3 Farming
  - ISO/TS 22002 - 4 Food packaging manufacturing
  - ISO/TS 22002 - 5 Food transport and storage
  - ISO/TS 22002 - 6 Feed and animal feed production
- The company may have to devote additional financial resources and time to improve if the current PRPs are inadequate (e.g. improvement of factory layout, walls, ventilation system, lightning, waste collection, personnel hygiene facilities etc.)

# Step 6: Conduct an organizational risk assessment

- Having an understanding of the uncertainties enables the organization to manage them better.
- You need to ask yourself: **What could prevent the organization from achieving food safety objectives?**
- Some concerns are:
  - Resources unavailability
  - Lack of competent staff
  - Inadequate infrastructure
  - Unfair business practices e.g. food fraud
  - Inadequate testing capacity
  - Inconsistent supplies of raw material
  - High staff turnover
  - Lack of staff motivation
  - Lack of standards
  - Lack of knowledge of the market requirements

# Step 7: Conduct an operational risk assessment (hazard analysis)

Risks associated with the operations are assessed using the **Hazard Analysis of Critical Control Points (HACCP) principles**.*

- Carry out a detailed hazard analysis of each step of the process, first. This will lead to the identification of significant hazards.
- Determine and set up control measures for the significant hazards.
- Establish and implement a Hazard Control Plan that includes critical limits, monitoring, corrections, verifications and corrective actions.
- Records of all these activities must be maintained.

*For a detailed description of the application of HACCP see: *IPD guide on HACCP*

# Step 8: Documentation

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- A proper system of documents and information management should be maintained.
- Specific standards/certification schemes may have specific document requirements.
- The documentation includes:
  - Food safety policy and related objectives
  - Documented procedures
  - HACCP plan(s)
  - Records to demonstrate the compliance of your with and the other requirements FSMS
- The company may also decide on:
  - Additional documents that cover additional procedures

# Step 9: Training, awareness generation and implementation

- All employees carrying out activities having an impact on food safety should be competent to do their jobs, therefore:
  - Provide correct procedures to follow when doing their work and how to keep accurate records
  - Provide training on monitoring
  - Create awareness on the importance of their activities and how they impact on food safety
- Records should be maintained as evidence of the operating FSMS.
- Records of training must be kept.
- It is recommended that training should be continuous, including refresher.

# Step 10: Internal FSMS audit

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**An internal audit is a systematic review of the system**. The purpose is to determine if the FSMS is being implemented correctly and if the results being achieved are as desired.

- The internal audit process determines how well your FSMS is working.
- Some of your employees can be trained to carry out internal audits.
- During the early period of FSMS implementation, audits may be done more frequently.
- Once the system stabilizes, the frequency of the audit can be adjusted accordingly. The decision with regard to the frequency should be defined in a yearly schedule that can then be distributed among the audit team.

# Step 11: Corrective action

**Corrective actions are the actions being taken to rectify and improve any negative observations** from internal audits or monitoring activities.

**A corrective action may include two steps**

1. Immediate action to remedy the situation back to normal.
2. Systematic determination of the cause and fixing the root cause, so that it doe
   again.

**In case a correction action is taken**

+ Records of actions taken need to be noted down.
+ Persons who authorized the corrections should be documented.
+ Results of verification after correction need to be maintained.

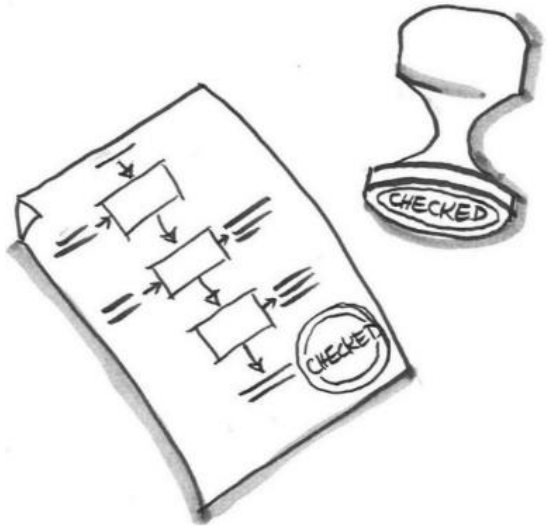
# Step 12: Management review

- The top management should, from time to time, review the:
  - Effectiveness of the FSMS as assessed through monitoring, verification and internal audits.
  - Changes in the operating environment, laws, customer requirements, emerging risks.
  - Actions for continual improvement.
  - Lessons learned from emergency situations, or accidents (if any).
  - Resource adequacy and needs.
  - Communication from internal and external parties including customer complaints and requests.
  - The status of the actions from previous management review.
- Decisions should then be taken to improve the FSMS.
- The **reviews need to be systematic on a periodic basis** and records need to be maintained.

# Step 13: Apply for certification

**Certification** of an FSMS is a confirmation (attestation) by a third party certification body that the company system meets the specified requirements, and is capable to assure safe food.

- Certification to FSMS is voluntary but often required by European importers.
- When looking for a certification body, make sure that it is internationally accredited, this enhances the credibility and recognition of the certification globally.
- Examples of certifications for food safety include: ISO 22000, FSSC 22000, BRC Global standard, IFS among others (see next slides for an overview)
- Steps of certification: see Sl. 32 + 33



# Comparison of some food safety certifications

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| | ISO22000 | FSSC22000 | BRCGS | IFS |
|---|---|---|---|---|
| **Standards used for certification** | ISO 22000<br>ISO/TS 22002 | ISO 22000<br>ISO/TS 22002 | BRC Global Standard | IFS Food Standard |
| **Requirements on top of FSMS** | None | FSSC additional requirements | None | None |
| **Scheme owners** | None | FSSC Foundation | BRCGS, subsidiary of LGC group | IFS (International Featured Standards) |
| **GFSI recognized** | No | Yes | Yes | Yes |
| **Focus** | Food safety and legal compliance | Food safety and legal compliance | Quality, food safety and legality | Product safety and quality |
| **Certificate validity** | 3 years | 3 years | 1 year | 1 year |
| **Relevance per region/country** | Universal | Universal, but has gained more prominence in Eurpean markets | Relevant especially for business with retailers. Originating from United Kingdom but now gaining more global presence. | Relevant especially for producers of private labels for retailers and distributors in: Germany, Netherlands, Switzerland, France, Italy, United States |

- Before deciding on the certification scheme to apply for, always check the customer and market preference

# ISO 22000: 2018

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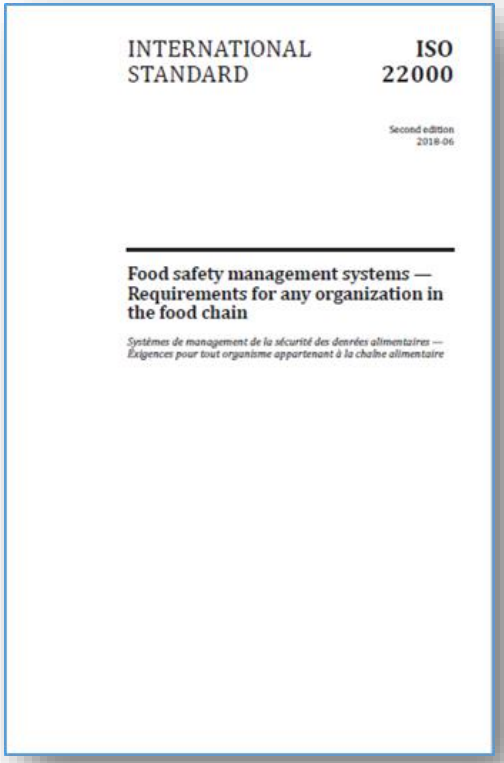
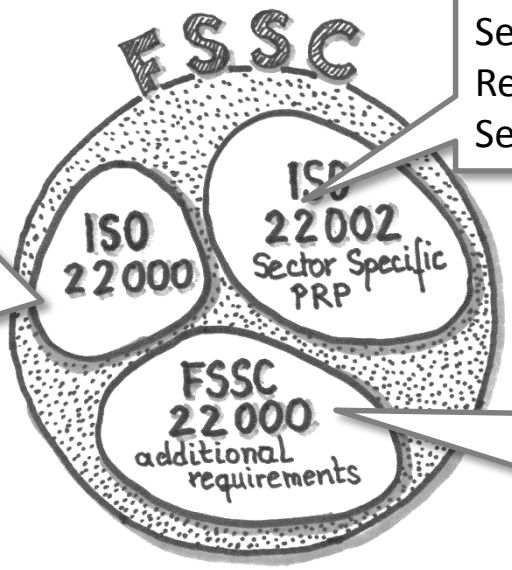
- This document specifies requirements for a FSMS in general. A FSMS incorporates the principles of HACCP, PRPs and management system requirements. If your company wishes to receive a certificate of compliance with the standard, it is mandatory to follow the ISO 22000 requirements.
- Certification to ISO 22000 can be done by any accredited certification body with FSMS scope.

➢ Find out more on: [https://www.iso.org/iso-22000-food-safety-management.html](https://www.iso.org/iso-22000-food-safety-management.html)



# FSSC 22000

- FSSC 22000 was developed to facilitate broader acceptance of ISO 22000, and recognition by the Global Food Safety Initiative (GFSI).
- FSSC 22000 is owned by a legal entity under Dutch law, called the Foundation FSSC 22000. Training and certification to FSSC 22000 can only be done by recognized institutions of the foundation.
- FSSC includes 3 required components:




ISO 22000 provides a common framework across the entire supply chain to manage requirements for food safety
→ See p. 3 & 24

Sector specific Pre-Requisite Programs → See p. 14

FSSC 22000 adds specific requirements to ensure consistency, integrity and to provide governance and management of the scheme
→ See p. 26

# FSSC 22000 additional requirements

- Management of services
- Food product labelling
- Food defense
- Food fraud mitigation
- Logo use
- Management of allergens*
- Environmental monitoring*
- Formulation of products*
- Transport and delivery*

➢ Find out more about Foundation FSSC 22000 on: https://www.fssc22000.com/scheme/

* Dependent on the food chain category

# British Retail Consortium Global Standard (BRCGS)

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- The British Retail Consortium Global Standard (BRCGS) provides a framework to manage product safety, integrity, legality and quality, and the operational controls in the food and food ingredient manufacturing, processing and packing industry (scope reaching from raw material to customer brands and also pet food).
- It was founded in 1996 by British retailers who wanted to harmonize food safety standards across the supply chain.
- Certification to BRCGS can only be done by BRCGS approved certification bodies.
- Very relevant standard when doing business with British retailers; but also other European retailers, manufactures and food processors may require a certification according to BRCGS from partners in their value chains.
- Compared to ISO 22000, the standard is not only result-oriented but also determines specific infrastructural resources/processes that support producers to attain the results.
- Around 60% of the criteria  is already covered in case you are ISO 9001 certified.

➢ Find out more on: https://brcdirectory.co.uk/

# International Featured Standard (IFS)

- The IFS Food Standard is a GFSI recognized standard for distributors and wholesalers with a focus on 'own' brand food products for consumers (private labels). It applies to food processing companies that pack loose food products, where product contamination may occur during primary packing.
- It was created in 2003 with full and active involvement of certification bodies, retailers, food industry and food service companies.
- Certification to IFS can only be done by IFS approved certification bodies.
- The IFS is important for all food manufacturers, especially for those producing private labels, as it contains many requirements related to the compliance with customer specifications.
- Similar to BRCGS, the standard is not only result-oriented but also determines specific infrastructural resources/processes that guide producers to attain the results.
- Compared to BRCGS, the standard does not focus on requirements by British importers and retailers, but includes requirements for several European countries as well as for the US market.

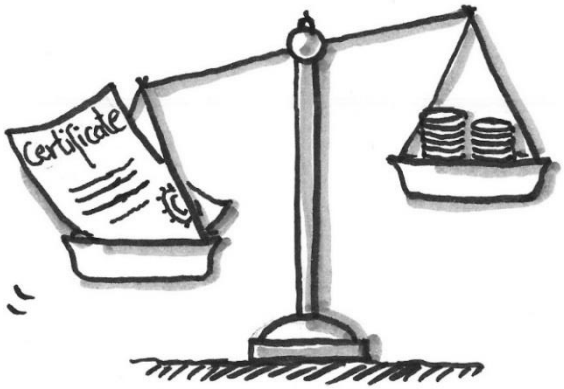
➢ Find out more on: https://www.ifs-certification.com/index.php/en/standards/251-ifs-food-en

# Certification process steps

Once all FSMS requirements are adequately implemented, you can apply for certification.

1. Select a certification body
2. Share required information and complete the application form
3. Negotiate and sign the certification contract
4. Pay the certification fee
5. Prepare required documentation and select available staff for the audit
6. Two stage audit process
   - **Stage 1** verifies that the system of the company has been designed and developed and is prepared to proceed to stage 2 audit.
   - **Stage 2** checks the implementation of the food safety management system.
7. Undertake any corrective actions or plan for them
8. Approval of the corrections, or corrective action plan
9. Issuance of certificate
10. Surveillance audits as per certification contract  at least 1 per year.
11. Recertification audit must be conducted prior to expiry of certificate

# Is certification viable?




**Audits as well as certification may add up to substantial costs to be paid for. Therefore, before applying for food safety certification, it is important to do a cost-benefit analysis to clarify whether a certification really pays.**

These factors should be taken into account:

+ Economical parameters such as the potential premium price if certified
+ Eventual shifts in required labor or inputs (e.g. trained staff)
+ Changed market conditions when being certified (demand, competition)
+ Market access opportunities of a certified product
+ Selection of certifier (consider costs but also: accreditation, reputation, existence of local offices, service orientation)

→ Speak to your current and potential new clients to find out whether they would pay a premium or order more products in case of certification!

# Cost and benefit when comparing certified with non-certified products

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## Costs

- Audit costs
- Potential investment into infrastructure (production equipment, resources etc.)
- Additional workload due to documentation requirements and internal audits
- Costs arising from changed processing procedures and packaging requirements
- Training of employees/producers
- Credit costs (if any)

## Benefits

- Third party assurance ( confidence)
- Adapting to increasing requirements of clients/target markets (e.g. EU) → Broader range of potential clients once certified
- Added value and unique selling point
- Improved health and safety of employees and producers
- Improved quality and safety of the products → less risk of harming consumers, reduced threat to product recalls
- Potentially more efficient production and processing procedures

# Information
# Links of useful websites

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- If you would like to get **more information on food safety**, we recommend the following websites and links:
  - http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/
  - https://ec.europa.eu/food/safety/general_food_law_en
  - https://www.iso.org/iso-22000-food-safety-management.html
  - https://www.fda.gov/food
  - https://www.brcgs.com/brcgs/food-safety/
  - https://www.fssc22000.com/
  - https://www.ifs-certification.com/index.php/en/standards/251-ifs-food-en

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**This guide was published by:**

**IPD - Import Promotion Desk**
Project Office Bonn
c/o sequa gGmbH
Alexanderstraße 10
D - 53111 Bonn
Germany
T: +49 (0) 228 965 05 890
F: +49 (0) 228 926 37 989
info@importpromotiondesk.de
www.importproomotiondesk.com

© Spetember 2020
External content adviser: Margaret Kola Ouma
Illustrations: Sabine Schacknat, sequa gGmbH

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