

FOOD SAFETY SYSTEM CERTIFICATION 22000

FSSC 22000

Certification scheme for food safety systems
in compliance with
ISO 22000: 2005 and technical specifications for
sector PRPs

Features

Foundation for Food Safety Certification

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FOOD SAFETY SYSTEM CERTIFICATION 22000

Certification scheme for food safety systems in compliance with ISO 22000:2005 and technical specifications for sector PRPs

This document contains a complete certification scheme for food safety and quality management systems which are in compliance with the publicly available food safety management systems standard ISO 22000: 2005 'Requirements for any organisation in the food chain', ISO 9001:2008 "Quality management systems – Requirements and technical specifications for sector PRPs (published as e.g. "PASxyz" or "ISO 22002-x" documents)

As of February 2010 it is a Global Food Safety Initiative approved scheme. The scheme was re-benchmarked and recognized by GFSI again in February 2013 against Guidance Document version 6.

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Due to the dynamic content of this document the user of this document should always verify if the correct version is held. Future revisions of this document will always be published under the same name.

In all cases the English version of the FSSC 22000 certification scheme is leading.

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INTRODUCTION

Food safety is a global concern, not only because of the importance for public health, but also because of its impact on international trade. Globalisation of food production and procurement makes food chains longer and more complex and increases the risk of food safety incidents. Effective and harmonized food safety systems shall manage and ensure the safety and suitability of food in each link of the supply chain. For this reason ISO developed the standard for food safety management systems ISO 22000, which applies to all organizations in the food chain and thus ensures integrity of the chain.

Parallel to this development there is an increasing need for harmonized certification of the food safety systems in order to create justified confidence that all necessary measures are taken to ensure food safety in previous links of the chain. In this context ISO developed the technical specification ISO/TS 22003 that contains requirements for bodies providing certification of the food safety management systems.

These developments were triggered by the increasing need of organizations in the food chain for a generally accepted food safety certificate that meets the requirements of the customers in the chain and may incorporate the requirements of the different certification schemes of the retail organizations.

As a follow up FoodDrinkEurope took the initiative to develop a technical specification that specifies the requirements for good practices in food manufacturing and that meets customer requirements. Implementation of these good practices is an essential part of the food safety system and creates confidence in trade. The British Standards Institution (BSI) issued these requirements as the publicly available specification BSI-PAS 220

As a next step FoodDrinkEurope initiated the development of a certification scheme for food safety systems of organizations in the food chain that incorporates the standards ISO 22000, BSI-PAS 220 and guidance on the application of ISO 22000, ISO/TS 22004. The aim of this scheme is to harmonize the certification requirements and methods for food safety systems in the food chain and to ensure the issue of trustworthy food safety certificates that are comparable as regards content and scope.

The Foundation was commissioned by FoodDrinkEurope to develop this scheme and retains the legal ownership and the license agreements for the certification bodies. In this text this certification scheme is referred to as the scheme. The scheme meets

the requirements of the guidance document of the Global Food Safety Initiative (GFSI).

In addition to the developments described above stakeholder organizations from other parts of the food supply chain have developed technical specifications covering requirements for PRPs for other parts of the supply chain. These technical specifications can be used in addition to ISO 22000 to provide further detail for chapter 7.2 of ISO 22000.

FSSC 22000 provides a certification model that can be used in the whole food supply chain. It can cover sectors where such a technical specification for sector PRPs has been realized. FSSC 22000 follows the supply chain category description as defined in ISO/TS 22003. As the development of new technical specifications for sector PRPs is on going the actual scope of FSSC 22000 and the applicable technical specifications for sector PRPs are described in Part I, chapter 2: Scope.

Note: PAS 220, referred to in this introduction, has been replaced by ISO TS 22002-1: 2009. The PAS was withdrawn at the end of 2012. Requirements are consistent across the old and new documents, so certifications using the PAS remain valid until their scheduled recertification audit date, when they must be revised to quote the ISO document.

Note: Scheme documents refer to food safety, but February 26, 2015 a voluntary food quality module was added to the FSSC 22000 scheme. Food safety can be read as food safety and quality in cases where food quality is voluntarily added to the scope of certification.

FEATURES OF THE SCHEME

Objective

This certification scheme outlines the requirements for certification bodies (CBs) to develop, implement and operate a system for the assessment and certification of food safety systems of organizations in the food chain and to guarantee its impartiality and competence. The certificate indicates that the organizations food safety system is in conformance with the requirements which are given in this scheme and that the organization is able to maintain conformance with these requirements. It is however not a guarantee of the organization continuous food safety performance. The value added to an organization with a certified food safety system lies in the efforts made by the organization to maintain that system and its commitment to continuously improve its performance.

Note: Scheme documents refer to food, but this can be read as food or feed as appropriate. Where scheme documents refer to 'human' or 'consumer' this may be read as 'human and/or animal' or 'consumer and/or animal' as appropriate.

Scope

This scheme is intended for the audit and certification of food safety systems, which ensure the safety of products during:

- the manufacturing of perishable animal products (e.g. meat, poultry, eggs, dairy and fish products)
- the manufacturing of perishable vegetal products (e.g. packaged fresh fruits and fresh juices, preserved fruits, packaged fresh vegetables, preserved vegetables)
- the manufacturing of products with long shelf life at ambient temperature (e.g. canned products, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar, salt)
- (bio)chemical manufacturing (food ingredients e.g. vitamins, additives and bio-cultures) but excluding technical and technological aids
- the manufacturing of food packaging (e.g. direct, indirect contact with the food)
- the manufacturing of food and feed for animals (e.g. animal feed, fish feed)
- the primary production of animal products (e.g. milk, fish, eggs, honey); Animal production.

Note: transport and storage on site and as part of the operation are included (e.g. cheese ripening). It is applicable to all organizations in the food chain in these categories, regardless of size and complexity, whether profit-making or not and whether public or private.

Note: Activities, such as fishing and hunting, which are not considered as organized farming activities are not included in the scope of primary production of animal products.

Content and plan

The scheme consists of an introductory part, four separate parts and a Quality module in which requirements and/or regulations for the actors in the process of certification have been laid down. These actors are: the organization in the food chain, the certification body (CB), the accreditation body (AB) and the Board of Stakeholders (Board).

The introductory part contains a description of the scheme and information on the background, definitions and reference documents.

The three following main sections contain the normative documents for:

- the organization in the food chain (Part I),
- the CB (Part II) and
- the AB (Part III).

These normative documents are indicated in the scheme as "Requirements".

Guidance on the application of these requirements is included if deemed necessary.

Apart from this the main sections contain:

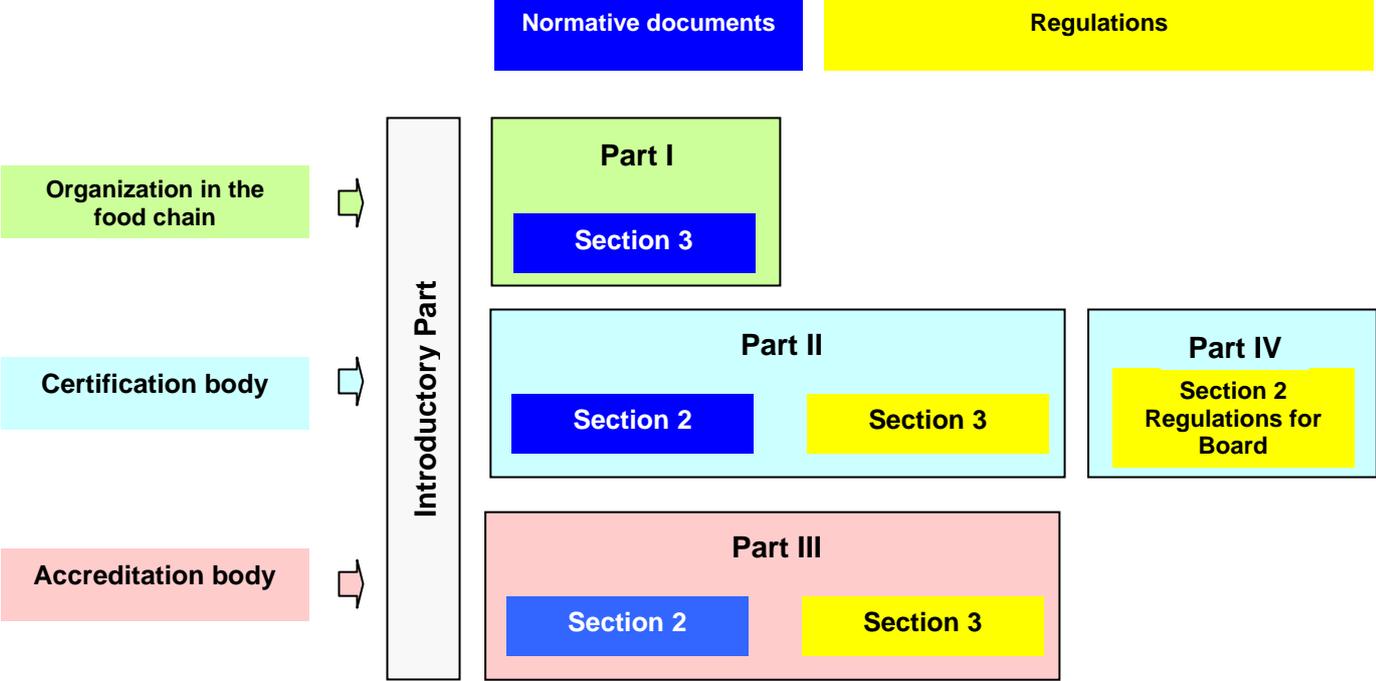
- guidance for the organization in the food chain to obtain and maintain a FSSC 22000 certificate (Part I),
- regulations of the Foundation concerning the conditions for the use of the scheme and for providing certification and accreditation by the CB and AB (Parts II and III).

Finally, Part IV contains the regulations for the Board, which deals with the requirements and regulations of this scheme.

In figure 1 an outline of the scheme is presented.

Figure 1 - Plan of certification scheme FSSC 22000

NOTE: the figure does not show the guidance which is included in the normative documents



Development

This certification scheme has been developed by project teams and steering committees comprising of food safety experts of representative international organizations in the food chain, experts of a number of international certification bodies, a representative of the confederation of the food and drink industry of the EU and sector experts. The scheme is approved by and will be maintained by the Board of Stakeholders. Within the board the interests of all involved parties are represented.

As of February 2010 it is a Global Food Safety Initiative approved scheme. The scheme was re-benchmarked and recognized by GFSI again in February 2013 against Guidance Document version 6.

Board of Stakeholders

The Foundation aims to prepare a certification scheme, with a broad acceptance adding particular value to the relationship between the certified organization in the food chain and those around it (the government, customers). In order to achieve this, the Board of the Foundation consists of representatives of trade and industry, authorities and other parties concerned.

Maintenance and review

The Board has at least three meetings per year to maintain the certification scheme. During every meeting major and/or minor changes are decided on. These decisions will be directly published in a current list on the Foundation website. Revisions of all relevant documents of the scheme are published annually on the Foundation website and communicated with the licensed CBs and ABs. If the Board considers it necessary that requirements or regulations should be amended or added on shorter notice than one year, the Board can issue a directive that will be effective from a given date. These directives will be communicated with the licensed CBs and ABs and will be published on the Foundation website. The Board will have an overall review of the certification scheme at intervals not exceeding three years and any amendments arising from the review will be published by the Foundation and made available to all stakeholders.

Operation

By entering into an agreement with the Foundation accredited CBs are authorized to provide certification in accordance with this scheme. Accreditation shall be gained in conformance with this scheme by an associated AB that complies with the regulation for ABs (Part III). Licensed CBs are obliged to adhere strictly to this scheme.

REQUIREMENTS AND REGULATIONS

The requirements and regulations are included in the following parts and are attached to this document:

Part I – Requirements for organizations that require certification

Part II – Requirements and regulations for certification bodies

Part III – Requirements and regulations for providing accreditation

Part IV – Regulations for the Board of Stakeholders

LIST OF DECISIONS BY THE BOARD OF STAKEHOLDERS

In the list all decisions of the Board of Stakeholders are included. The decisions which affect the associated certification bodies as well as the certificate holders are an integral part of the requirements for certification. After every meeting of the Board an updated list is published on the website www.fssc22000.com.

REFERENCE DOCUMENTS

This scheme is based on the following documents and their future versions:

- GFSI Guidance Document, Sixth Edition, January 2011
- IAF Mandatory Document for duration of QMS and EMS audits; 2009 (Issue 1, IAF MD 5: 2009) and all other relevant IAF Mandatory Documents
- ISO 9001: 2008, Quality management systems – Requirements
- ISO 19011: 2002, Guidelines for quality and/or environmental management systems auditing
- ISO 22000: 2005, Food safety management systems – Requirements for any organisation in the food chain

Note: In the context of the scheme, the scope of ISO22000 is extended to include animal health when related to feed consumption

- ISO/TS 22002-1: 2009, Prerequisite programmes for food safety – Part 1: Food manufacturing
- ISO/TS 22002-3: 2011, Prerequisite programmes for food safety – Part 3: Farming
- ISO/TS 22002-4: 2013, Prerequisite programmes for food safety – Part 4: Food packaging manufacturing
- ISO/TS 22003: 2007, Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems
- ISO/TS 22004: 2005, Food safety management systems – Guidance on the application of ISO 22000: 2005
- ISO/IEC 17000: 2004, Conformity assessment – Vocabulary and general principles
- ISO/IEC 17011: 2004, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
- ISO/IEC 17021: 2011, Conformity assessment – Requirements for bodies providing audit and certification of management systems
- BSI PAS 222:2011, Prerequisite programmes for food safety in the manufacture of food and feed for animals

TERMS AND DEFINITIONS

For the purpose of this document the terms and definitions given in the standards and technical specifications which are listed in the reference documents apply.

The following terms and definitions also apply:

- **Animal production:** All operations related to the farming of living farm animals (e.g. cattle, poultry, pigs, fish, bees) and the handling of their products (e.g. milk, eggs, fish, honey), as far as they are carried out on the farm premises (e.g. storage, sorting, cleaning, packing of unprocessed products, on-farm feed manufacturing, transport within the farm). However, fishing, hunting, transportation of animals to or from the farm, and processing activities carried out on farm premises (e.g. heating, smoking, curing, maturing, fermenting, drying, marinating, extraction, extrusion or a combination of those processes), are not included in the scope of this definition.
- **Audit:** systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled.
- **Board of Stakeholders or Board:** a group of representatives of key interests within the scope of the certification scheme including experts on food safety.
- **Certification system:** rules of procedure and management for carrying out conformity assessment leading to the issuance of a certification/registration document and its subsequent maintenance.
- **Certification scheme:** a set of requirements for the process of certification to certify conformance with a performance standard which is included or referred to in the scheme. Apart from the performance standard, the scheme may contain normative documents for the certification body and the accreditation body which certifies the certification body.
- **Facility:** A building or structure that provides a particular service or is used by a supplier
- **Feed:** Any substance or product, including feed additives, whether processed or unprocessed, intended to be used for direct or indirect feeding of animals.

- **Feed Manufacturing:** (Also called Feed Processing) The manufacture/processing of materials intended to be consumed by animals and contribute energy and/or nutrients to their diet.
- **Feed Safety:** A concept that feed will not cause harm to animals or adversely affect animal health when utilised according to its intended purpose.
- **Food:** any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances used only as drugs
- **Food Defence:** The process to ensure the security of food and feed and their supply chains from all forms of malicious attack including ideologically motivated attack leading to contamination or supply failure.
- **Food/Feed Safety Hazard:** The definition given in ISO22000 (3.3) shall apply with the following modifications:
Line 1: biological, chemical or physical agent in food/feed, or condition of food/feed, with the potential to cause an adverse health effect to humans and/or animals
 Note: In the context of feed and feed ingredients, relevant food/feed safety hazards are those that may be present in and/or on feed and feed ingredients and that may harm the animals and/or may subsequently be transferred to food through animal consumption of feed and may thus have the potential to cause an adverse human health effect.
- **Food manufacturing,** also called food processing: The set of methods and techniques used to make food. Food manufacturing typically takes [harvested](#) crops or animal products and uses these to produce food for sale or delivery to the consumer and ingredients for food manufacturing.
- **Food processing:** see definition of food manufacturing.
- **Foundation:** the Foundation for Food Safety Certification.
- **General principles of food hygiene of the Codex Alimentarius:** recommended International code of practice – General principles of food hygiene, CAC/RCP 1-1969, Rev. 4 (2003) of the Joint FAO/WHO Codex Alimentarius Commission.

- **Guidelines for drinking–water quality of the WHO:** guidelines for drinking water quality, Third edition, Volume 1, Recommendations, WHO, Geneva 2008.
- **Ingredient:** A component of food, feed or packaging that has undergone processing
- **Major nonconformity:** a nonconformity, as referred to in ISO/IEC 17021 clause 9.1.15b, that:
 - 1) represents failure to fulfil one or more requirements of the management system standard or
 - 2) a situation that raises significant doubt about the clients system to achieve its intended outputs.
- **Minor nonconformity:** other nonconformities as indicated in ISO/IEC 17021, clause 9.1.15c.
- **Normative document:** normative documents are indicated in the scheme as 'Requirements'.
- **Organization in the food chain:** the food or feed chain partner that is responsible for ensuring that products meet and, if applicable, continue to meet, the requirements on which the certification is based.
- **Periodically reviewed:** periodically reviewed includes minimum annually.
- **Quality:** the ability to consistently provide a product that meets customer and applicable statutory and regulatory requirements.
- **Raw Material:** A component of food, feed or packaging that has not undergone processing.
- **Rework:** [supplements PAS222 definition 2.17] The re–utilisation of feed, ingredients or raw materials
- **Risk:** the probability of causing an adverse health effect caused by the likelihood of occurrence and by the possible severity of the adverse health effect of a particular hazard in food when prepared and consumed according to its intended use.
- **Standard:** a document against which something can be measured, judged or evaluated. "Document" is to be understood as any medium with information recorded on or in it.

- **Vehicle:** Any device used for the conveyance of raw material, ingredients, food, feed or packaging that is capable of being moved upon roadways, railways or airways. Vehicles may be motorised or non motorised.