

FOOD SAFETY SYSTEM CERTIFICATION 22000

FSSC 22000

Certification scheme for food safety systems of
Food manufacturing
based on
ISO 22000: 2005 and BSI-PAS 220: 2008

Foundation for Food Safety Certification

Gorinchem, the Netherlands: January 2009

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This document contains a complete certification scheme for Food Safety Systems based on the publicly available food safety management standard ISO 22000: 2005 'Requirements for any organisation in the food chain' and the publicly available specification for Prerequisite programmes on food safety for food manufacturing, BSI-PAS 220: 2008.

It is intended for the certification of food safety systems of food manufacturers that process or manufacture animal products (not including slaughtering and pre-slaughtering), perishable vegetal products, products with a long shelf life and (other) food ingredients like additives, vitamins and bio-cultures.

As of [..... 2009] it is a Global Food Safety Initiative approved scheme.

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Secretary Board of Stakeholders and Foundation for Food Safety Certification

Gorinchem, January 2009

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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 organisations 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 food manufacturers for a generally accepted food safety certificate that meets with the requirements of the subsequent customers in the chain and may incorporate the requirements of the different certification schemes of the retail organisations.

As a follow up the Confederation of the Food and Drink Industry of the EU (CIAA) 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 practises is an essential part of the food safety system and creates confidence in trade. The British Standard Institution, BSI issued these requirements as the publicly available specification BSI-PAS 220.

As a next step CIAA initiated the development of a certification scheme for food safety systems of food manufacturers 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 CIAA 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).]

FEATURES OF THE SCHEME

Objective

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

Scope

This scheme is intended for the audit and certification of the food safety system of food manufacturers that manufacture:

- perishable animal products, excluding slaughtering and pre-slaughtering (i.e. meat, poultry, eggs, dairy and fish products);
- perishable vegetal products (i.e. packaged fresh fruits and fresh juices, preserved fruits, packaged fresh vegetables, preserved vegetables)
- products with long shelf life at ambient temperature (i.e. canned products, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar, salt)
- (bio)chemical products for food manufacturing (i.e. vitamins additives and bio-cultures) but excluding technical and technological aids

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

Content and plan

The scheme consists of an introductory part and four separate parts in which requirements and/or regulations for the actors in the process of certification have been laid down. These actors are: the foods manufacturing organisation, 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. Furthermore it contains the

running list of decisions by the Board.

The three following parts contain first of all the normative documents for the food manufacturing organisation (Part I), the CB (Part II) and the AB (Part III). These are indicated in the scheme as "Requirements". Guidance on the application of these requirements is included if deemed necessary.

Part I also contains a guidance for the food manufacturing organisation on how obtain and maintain a FSSC 22000 certificate.

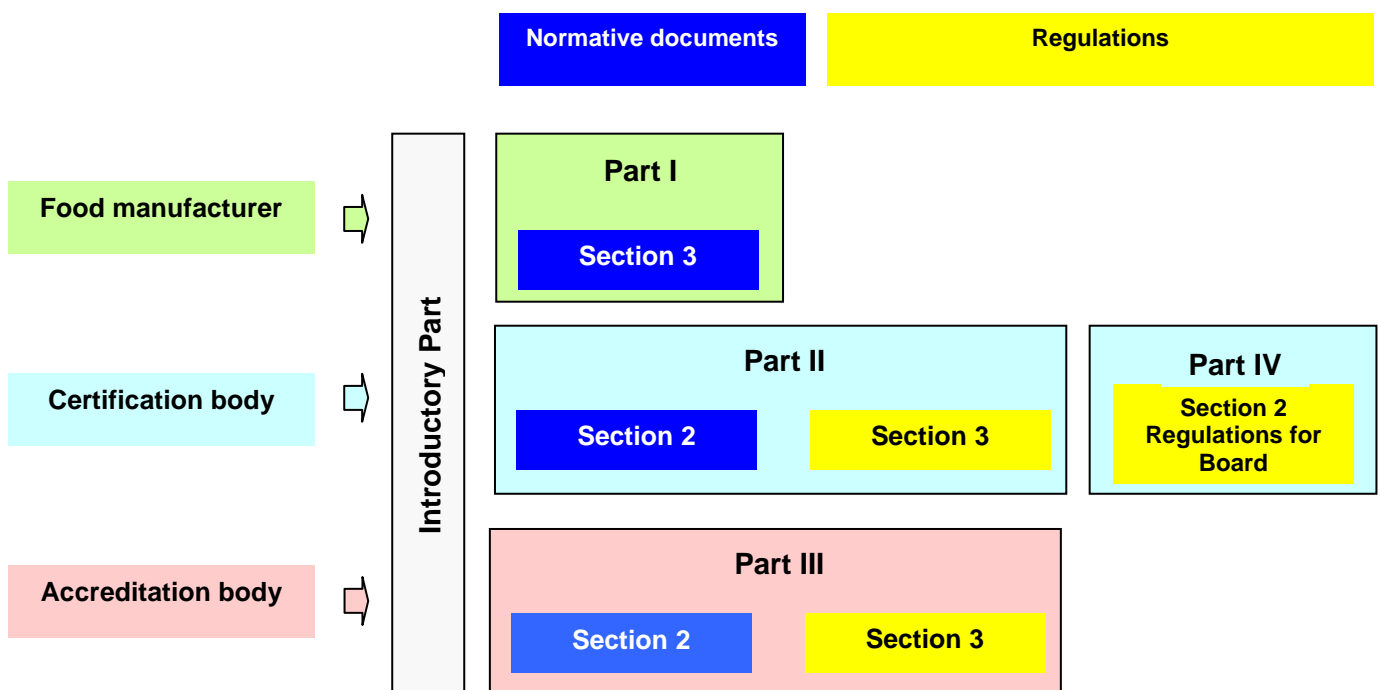
The Parts II and III, also contain regulations of the Foundation concerning the conditions for the use of the scheme and for providing certification and accreditation. by the CB and AB

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 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 a project team and steering committee comprising of food safety experts of representative international food manufacturers, experts of a number of international certification bodies a representative of the confederation of the food and drink industry of the EU. The scheme is approved by and will be maintained by the Board of Stakeholders of the scheme. Within the board the interests of all involved parties are represented. [As of it is a Global Food Safety Initiative approved scheme].

Board of Stakeholders

The Foundation aims to prepare a certificate scheme, with a broad acceptance adding particular value to the relationship between the certified food organisations and those around it (the government, customers and suppliers). In order to achieve this, the Board of the Foundation consists of representatives of trade and industry, authorities and other parties concerned. The Board complies with the requirements set by the accreditation bodies which are member of the IAF multilateral recognition agreement.

Maintenance and review

The Board has at least three meetings per year to maintain the certification scheme. After every meeting major and/or minor changes are decided on and will be directly published in a current list of decisions on the Foundation website. Revisions of all relevant documents of the scheme are published annually on the Foundation website and communicated with the licensed CB's and AB's. 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 CB's and AB's 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 CB's 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 AB's (Part III). Licensed CB's 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 to obtain certification

Part II – Requirements and regulations for providing certification

Part III – Requirements and regulations for providing accreditation

Part IV – Regulations for the Board of Stakeholders

CURRENT LIST OF DECISIONS BY THE BOARD OF STAKEHOLDERS

The Current list of decisions by the Board of Stakeholders will be attached to this document. In the list all valid 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:

- BSI-PAS 220: 2008, Prerequisite programmes on food safety for food manufacturing (Publicly Available Specification of British Standards Institution)
- General Principles of Food Hygiene, CAC/RCP 1-1969, Rev. 4 (2003) of the Joint FAO/WHO Codex Alimentarius Commission
- GFSI Guidance Document, Fifth Edition, September 2007
- Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application, Annex to CAC/RCP 1-1969, Rev. 4 (2003) of the Joint FAO/WHO Codex Alimentarius Commission
- IAF Guidance on the Application of ISO/IEC Guide 65:1996 (IAF GD 5: 2006)
- IAF Guidance on the Application of ISO/IEC Guide 62:1996 (IAF GD 2: 2005)
- IAF Mandatory Document for duration of QMS and EMS audits; 2009 (Issue 1, IAF MD 5: 2009)
- ISO Guide 65: 1996, General requirements for bodies operating product certification systems
- 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
- 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: 2006, Conformity assessment – Requirements for bodies providing audit and certification of management systems

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:

- **BSI-PAS 220:** Technical Specification BSI-PAS 220: 2008, Prerequisite programmes on food safety for food manufacturing.
- **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.
- **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 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
- **Food safety system:** all actions, measures and management tools of an organisation (i.e. food manufacturer; feed manufacturer) to ensure that the products that are delivered by the organisation to the consumer or to subsequent organisations are not harmful to the consumer.

- **Foundation:** The Foundation for Food Safety Certification.
- **IAF Guidance on ISO Guide 62:** IAF Guidance on the Application of ISO/IEC Guide 62:1996 (IAF GD 2: 2005)
- **IAF Guidance on ISO Guide 65:** IAF Guidance on the Application of ISO/IEC Guide 65:1996 (IAF GD 5: 2006)
- **ISO 22000:** Standard ISO 22000: 2005, Food safety management systems – Requirements for any organisation in the food chain.
- **ISO 9001:** Standard ISO 9001: 2008, Quality management systems – Requirements.
- **ISO/TS 22003:** Technical specification ISO/TS 22003: 2007, Food safety management systems –Requirements for bodies providing audit and certification of food safety management systems.
- **ISO 19011:** Standard ISO 19011: 2002, Guidelines for quality and/or environmental management system auditing.
- **ISO Guide 65:** Standard ISO Guide 65: 1996, General requirements for bodies operating product and process certification systems.
- **ISO/IEC 17011:** Standard ISO/IEC 17011: 2004, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.
- **ISO/IEC 17021:** Standard ISO/IEC 17021: 2006, Conformity assessment – Requirements for bodies providing audit and certification of management systems.
- **Minor nonconformity:** An observation, which leads to a minor nonconformity report, relating to a nonconformity in the situation that this does not effect the functioning of the system or the food safety of the product or service.
- **Nonconformity:** An observation, which leads to a nonconformity report, as defined in IAF Guidance on the Application of ISO/IEC Guide 65:1996 (IAF GD 5: 2006).

- **Normative document:** See definition of standard.
- **Standard**, also called normative document: 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.
- **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.