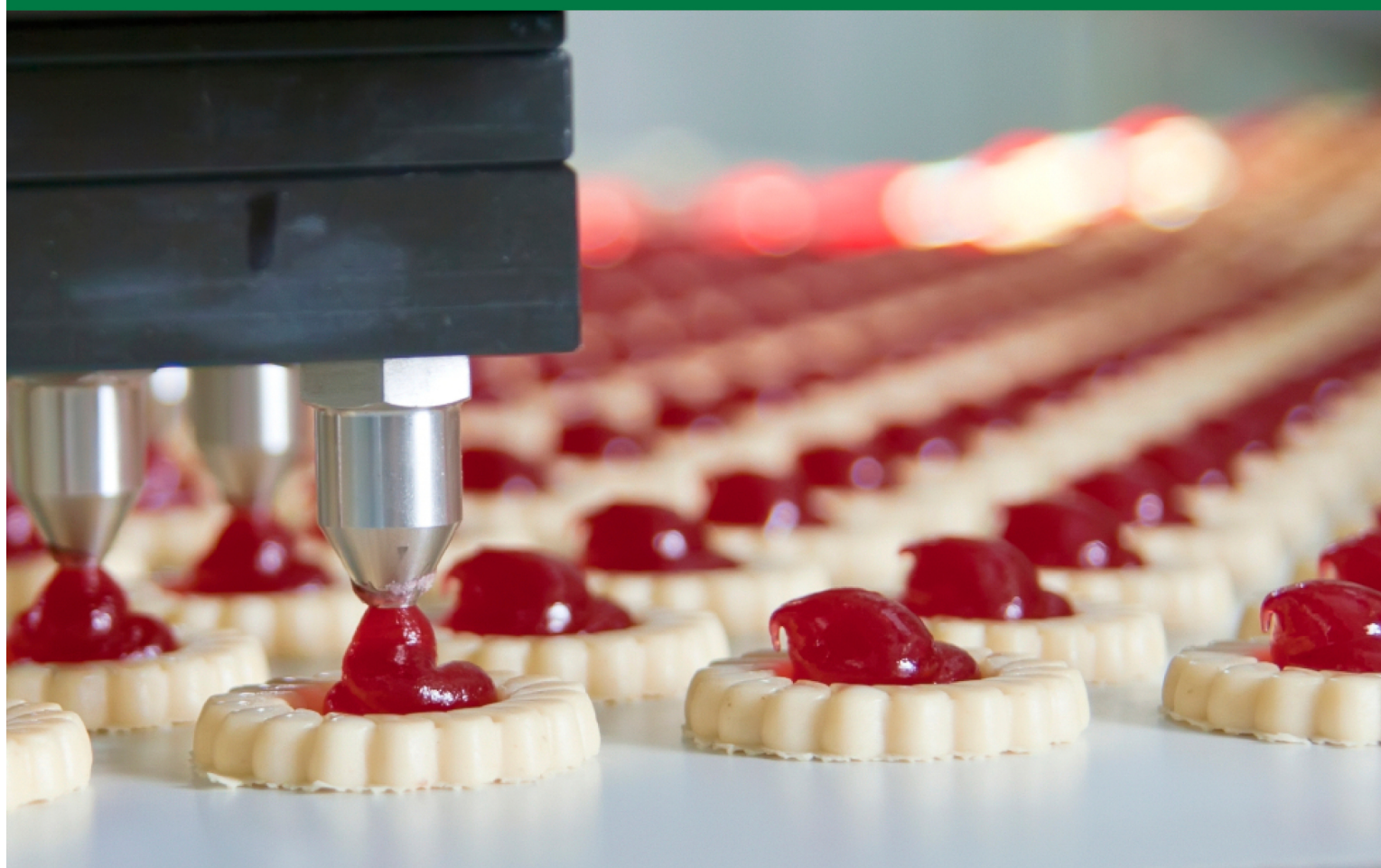




FOOD SAFETY SYSTEM CERTIFICATION 22000

Part II: Requirements for Certification



Version 4.1: July 2017

Part II: Requirements for Certification

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1 Purpose

This document states the requirements to be included in the design and implementation of the Food Safety Management System claimed to conform with the requirements of the Scheme by an applicant/certified organization seeking to be included in the FSSC 22000 Register of Certified Organizations.

1.1 Food categories and sectors

The following food chain categories and related supply chain sectors fall within the Scheme scope of certification:

| Category | Sub-category | Supply chain sector | Food Safety / Quality Management System | Pre-requisite programs | Additional requirements |
|----------|--------------|--|---|---|-----------------------------|
| A | AI | Farming of animals for meat/milk/eggs/honey | ISO 22000:2005 / ISO 9001:2015 | ISO/TS 22002-3:2011 | See 2.1.4 for applicability |
| | AII | Farming of fish and seafood | ISO 22000:2005 / ISO 9001:2015 | ISO/TS 22002-3:2011 | See 2.1.4 for applicability |
| C | CI | Processing of perishable animal products | ISO 22000:2005 / ISO 9001:2015 | ISO/TS 22002-1:2009 | See 2.1.4 for applicability |
| | CII | Processing of perishable plant products | ISO 22000:2005 / ISO 9001:2015 | ISO/TS 22002-1:2009 | See 2.1.4 for applicability |
| | CIII | Processing of perishable animal and plant products (mixed products) | ISO 22000:2005 / ISO 9001:2015 | ISO/TS 22002-1:2009 | See 2.1.4 for applicability |
| | CIV | Processing of ambient stable products | ISO 22000:2005 / ISO 9001:2015 | ISO/TS 22002-1:2009 | See 2.1.4 for applicability |
| D | DI | Production of animal feed | ISO 22000:2005 / ISO 9001:2015 | ISO/TS 22002-6:2016 (BSI/PAS 222:2011*) | See 2.1.4 for applicability |
| | DII | Production of pet food for dogs and cats | ISO 22000:2005 / ISO 9001:2015 | ISO/TS 22002-1 | See 2.1.4 for applicability |
| | DII | Production of pet food for other pets than dogs and cats | ISO 22000:2005 / ISO 9001:2015 | ISO/TS 22002-6:2016 (BSI/PAS 222:2011*) | See 2.1.4 for applicability |
| E | N/A** | Catering | ISO 22000:2005 / ISO 9001:2015 | ISO/TS 22002-2:2013 | See 2.1.4 for applicability |
| F | FI | Retail | ISO 22000:2005 / ISO 9001:2015 | BSI/PAS 221:2013 | See 2.1.4 for applicability |
| G | GI | Provision of transport and storage services for perishable food and feed | ISO 22000:2005 / ISO 9001:2015 | NEN/NTA 8059:2016 | See 2.1.4 for applicability |
| | GII | Provision of transport and storage services for ambient food and feed | ISO 22000:2005 / ISO 9001:2015 | NEN/NTA 8059:2016 | See 2.1.4 for applicability |
| I | N/A** | Production of food and feed packaging and packaging material | ISO 22000:2005 / ISO 9001:2015 | ISO/TS 22002-4:2013 | See 2.1.4 for applicability |
| K | N/A** | Production of (bio)chemicals | ISO 22000:2005 / ISO 9001:2015 | ISO/TS 22002-1:2009 | See 2.1.4 for applicability |

* The BSI/PAS 222:2011 standard shall no longer be used after January 1, 2018

** N/A = Not Applicable

1.2 Field of application

The Scheme requirements are global in nature, applicable to organizations in the food and feed supply chain regardless of their size and complexity, whether profit-making or not and whether public or private.

2 Outline of Scheme requirements

This section provides an outline of the Scheme requirements to be met in order to achieve certification.

2.1 Main components

The Scheme requirements consist of separate components that shall be audited as a single system:

- 1) ISO 22000:2005 food safety management system requirements.
- 2) ISO 9001:2015 quality management systems requirements – when selected (FSSC 22000 Quality).
- 3) Sector specific pre-requisite programs (PRPs) requirements.
- 4) Additional requirements.

The following clauses provide a brief commentary on each component and state the high level requirements to be met for each.

2.1.1 ISO 22000

The requirements for the development, implementation and maintenance of the food safety management system are laid down in the standard ISO 22000:2005 “Food safety management systems - Requirements for any organization in the food chain”.

To facilitate the successful implementation of a food safety management system, the operational conditions of the food safety management system shall be specified, documented and verified.

2.1.2 ISO 9001

For FSSC 22000-Quality certification, all ISO 9001:2015 Quality Management System requirements are applicable in addition to the Scheme requirements.

2.1.3 Prerequisite Programs (PRP)

ISO 22000 requires in clause 7.2 that organizations shall select and implement specific PRPs for basic hygiene conditions.

Organizations establishing, implementing and maintaining these PRPs shall consider other appropriate information and utilize it accordingly. Such information shall include:

- a) regulatory requirements;
- b) recognized sector or product group codes of practices and guidelines;
- c) customer requirements.

To facilitate the successful implementation of the food safety management system, the conditions of the PRPs shall be;

- a) specified,
- b) documented,
- c) approved and
- d) verified.

ISO 22000:2005 does not specify these requirements as the standard is applicable to the whole food chain and the basic hygiene requirements may vary considerably between sectors.

In order to clarify the requirements for PRPs and to allow for recognition by the Global Food Safety Initiative (GFSI) of the Consumer Goods Forum, industry stakeholders have

developed detailed technical specifications covering sector pre-requisite programs (PRPs).

These technical specifications are used in addition to ISO 22000 to provide an agreed interpretation. Exceptions shall be justified and documented where PRP requirements are deemed not to be applicable in relation to the scope of the organization's activities and verified during an audit.

FSSC 22000 provides a certification Scheme for sectors where such a technical specification for sector PRPs has been integrated as described in the scope (see table 1 above).

2.1.4 Additional requirements

To meet the needs of the key stakeholders and to ensure an adequate control of food safety, specific additional FSSC requirements for the food safety management system are included in the Scheme.

These may be elaborations of the clauses in ISO 22000:2005 and technical specifications for sector PRPs or additional requirements as outlined below.

The additional Scheme requirements are:

- 1) Management of services,
- 2) Product labelling,
- 3) Food defense,
- 4) Food fraud prevention,
- 5) Logo use,
- 6) Management of allergens (for categories C, I and K only),
- 7) Environmental monitoring (for categories C, I and K only),
- 8) Formulation of products (for category DII only),
- 9) Management of natural resources (for category A only).

2.1.4.1 Management of services

- 1) The organization in the food chain shall ensure that all services that may have an impact on food safety:
 - a) have specified requirements which are regularly reviewed,
 - b) are described in documents to the extent needed to conduct hazard analysis,
 - c) are managed in conformance with the requirements of technical specification for sector PRPs,
 - d) are assessed and approved demonstrating compliance with specified requirements,
 - e) are monitored to assure continued service provider approval status.
- 2) The services referred to in 1) above shall include at least:
 - a) utilities,
 - b) transport and storage,
 - c) maintenance,
 - d) cleaning and
 - e) outsourced services.
- 3) The organization shall implement a system to assure that when analysis critical to the verification of food safety is undertaken, this is conducted by a competent laboratory that has the capability to produce precise and repeatable test results using validated test methods and best practices (e.g. successful participation in proficiency testing programs, regulatory approved programs or accreditation to international standards such as ISO 17025).

2.1.4.2 Product labelling

The organization shall ensure that the finished product is labelled according to the applicable food regulations in the country of intended sale.

2.1.4.3 Food defense

2.1.4.3.1 Threat assessment

- 1) The organization shall have a documented and implemented threat assessment procedure in place that:
 - a) identifies potential threats,
 - b) develops control measures, and
 - c) prioritises them against the identified threats.
- 2) To identify the threats, the organization shall assess the susceptibility of its products to potential food defense acts.

2.1.4.3.2 Control measures

The organization shall put in place appropriate control measures to reduce or eliminate the identified threats.

2.1.4.3.3 Plan

- 1) All policies, procedures and records are included in a food defense plan supported by the organization's Food Safety Management System for all its products.
- 2) The plan shall comply with applicable legislation.

2.1.4.4 Food Fraud prevention

2.1.4.4.1 Vulnerability assessment

- 1) The organization shall have a documented and implemented vulnerability assessment procedure in place that:
 - a) identifies potential vulnerabilities,
 - b) develops control measures, and
 - c) prioritises them against the identified vulnerabilities.
- 2) To identify the vulnerabilities, the organization shall assess the susceptibility of its products to potential food fraud acts.

2.1.4.4.2 Control measures

The organization shall put in place appropriate control measures to reduce or eliminate the identified vulnerabilities.

2.1.4.4.3 Plan

- 1) All policies, procedures and records are included in a food fraud prevention plan supported by the organization's Food Safety Management System for all its products.
- 2) The plan shall comply with applicable legislation.

2.1.4.5 Logo use

- 1) Certified organizations are entitled to use the FSSC 22000 logo. The FSSC 22000 logo may be used on the organization's printed matter, website and other promotional material subject to the following design specifications:

| Colour | PMS | CMYK | RGB | # |
|--------------|-----------|------------|-------------|--------|
| Green | 348 U | 82/25/76/7 | 33/132/85 | 218455 |
| Grey | 60% black | 0/0/0/60 | 135/136/138 | 87888a |

- 2) Use of the logo in black and white is permitted when all other text and images are in black and white.
- 3) To avoid the impression that the CB has certified or approved any product, process or service supplied by the certified organization the FSSC 22000 logo is not allowed to be used on:
 - a) a product,
 - b) its labelling,
 - c) its packaging,
 - d) in any other manner that implies FSSC 22000 approves a product, process or service.

2.1.4.6 Management of allergens (for categories C, I and K only)

- 1) A documented allergen management plan shall be in place that includes:
 - a) risk assessment addressing potential allergen cross contamination;
 - b) control measures to reduce or eliminate the risk of cross contamination;
 - c) validation and verification of effective implementation.
- 2) All finished products intentionally or potentially containing allergenic materials are labeled according to the allergen labelling regulations in the country of manufacture and country of destination.

2.1.4.7 Environmental monitoring (for categories C, I and K only)

The organization shall ensure that an environmental monitoring program is in place to verify the effectiveness of cleaning and sanitation programs which shall meet the verification requirements as described in ISO 22000.

2.1.4.8 Formulation of products (for sub-category DII, pet food for dogs and cats only)

- 1) Compounded pet food for dogs and cats shall be formulated in a manner that is consistent with the intended use of the product.
- 2) Formulation procedures shall be in place to manage the use of ingredients that contain nutrients that can have adverse animal health impact.

2.1.4.9 Management of natural resources (for category A only)

- 1) The organization (animal farm) shall:
 - a) Identify the risks it exposes from animal production to both,
 - i) animal health, and
 - ii) public health.
 - b) Assess the hazards that expose these risks derived from on-farm used natural resources (e.g. water and soil, to include water for animals, water for irrigation, on farm feed production for own animals).
 - c) Put in place appropriate control measures to protect public and animal health.