Part 2: 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 fall within the Scheme scope of certification.

Table 1: Food chain categories, ISO 22000 and PRP standards. Additional requirements apply to all categories.

<table>
<thead>
<tr>
<th>Category</th>
<th>Sub-category</th>
<th>Description</th>
<th>ISO 22000/ISO 9001</th>
<th>PRP</th>
<th>Additional requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>AI</td>
<td>Farming of animals for meat/milk/eggs/honey</td>
<td>Applicable</td>
<td>ISO/TS 22002-3</td>
<td>Applicable</td>
</tr>
<tr>
<td>AII</td>
<td>Farming of fish and seafood</td>
<td>Applicable</td>
<td>ISO/TS 22002-3</td>
<td>Applicable</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>CI</td>
<td>Processing of perishable animal products</td>
<td>Applicable</td>
<td>ISO/TS 22002-1</td>
<td>Applicable</td>
</tr>
<tr>
<td>CII</td>
<td>Processing of perishable plant products</td>
<td>Applicable</td>
<td>ISO/TS 22002-1</td>
<td>Applicable</td>
<td></td>
</tr>
<tr>
<td>CIII</td>
<td>Processing of perishable animal and plant products (mixed products)</td>
<td>Applicable</td>
<td>ISO/TS 22002-1</td>
<td>Applicable</td>
<td></td>
</tr>
<tr>
<td>CIV</td>
<td>Processing of ambient stable products</td>
<td>Applicable</td>
<td>ISO/TS 22002-1</td>
<td>Applicable</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>DI</td>
<td>Production of animal feed</td>
<td>Applicable</td>
<td>PAS 222</td>
<td>Applicable</td>
</tr>
<tr>
<td>DII</td>
<td>Production of pet food for other pets than dogs and cats</td>
<td>Applicable</td>
<td>ISO/TS 22002-6</td>
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<tr>
<td>E</td>
<td>Catering</td>
<td>Applicable</td>
<td>ISO/TS 22002-2</td>
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<tr>
<td>FI</td>
<td>Retail</td>
<td>Applicable</td>
<td>PAS 221</td>
<td>Applicable</td>
<td></td>
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<tr>
<td>G</td>
<td>GI</td>
<td>Provision of Transport and Storage Services for Perishable Food and feed</td>
<td>Applicable</td>
<td>NTA 8059</td>
<td>Applicable</td>
</tr>
<tr>
<td>GII</td>
<td>Provision of Transport and Storage Services for Ambient Food and feed</td>
<td>Applicable</td>
<td>NTA 8059</td>
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<tr>
<td>I</td>
<td>Production of food packaging and packaging material</td>
<td>Applicable</td>
<td>ISO/TS 22002-4</td>
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</tr>
<tr>
<td>K</td>
<td>Production of (bio)chemicals</td>
<td>Applicable</td>
<td>ISO/TS 22002-1</td>
<td>Applicable</td>
<td></td>
</tr>
</tbody>
</table>

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 food safety management system requirements.
2) ISO 9001 quality management systems requirements – when selected (FSSC Quality).
3) Sector specific pre-requisite programs (PRPs) requirements.
4) Additional Scheme 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 “Food safety management systems - Requirements for any organization in the food chain”.
In order 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-Q certification, ISO 9001 is needed in addition to the ISO 22000 management system 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.
In order to facilitate the successful implementation of the food safety management system, the conditions of the PRPs shall be;
  a) specified,
  b) documented,
  c) validated and
  d) verified.
ISO 22000 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 a benchmark of ISO 22000 based certification schemes 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 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 and technical specifications for sector PRPs or additional requirements as outlined below.

The additional Scheme requirements are:

1) Management of services
2) Supervision of personnel
3) Management of supplied materials
4) Management of natural resources (for animal production only)
5) Food defense
6) Food fraud prevention
7) Formulation of products (only for pet food for dogs and cats)
8) Management of allergens
9) Product labelling
10) Environmental monitoring
11) Logo use.

#### 2.1.4.1 Management of services

The organization in the food chain shall ensure that all services that are provided and may have an impact on food safety:

- a) have specified requirements,
- 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 monitored.

The services referred to in 1) above shall include at least:

- a) utilities,
- b) transport,
- c) maintenance, and
- d) outsourced activities.

#### 2.1.4.2 Supervision of personnel

The organization in the food chain shall ensure the effective supervision of the personnel in the correct application of the food safety principles and practices commensurate with their activity.
2.1.4.3 Management of supplied materials

The organization shall ensure that all inputs (supplied materials) that may have an impact on food safety:

a) have specified requirements,
b) are described in documents to the extent needed to conduct hazard analysis.
c) comply with any applicable regulatory requirements (e.g. control of prohibited substances).

The organization shall implement a system to assure that analysis of all inputs critical to the verification of product safety is undertaken. The analyses shall be performed according to ISO 17025 or equivalent. Equivalent systems shall include at least participation to proficiency testing.

2.1.4.4 Management of natural resources (for animal production 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).

Put in place appropriate protective and control measures to protect public and animal health.

2.1.4.5 Food defense

2.1.4.5.1 Threat assessment

1) The organization shall document, establish and maintain a documented procedure for food defense threat assessment that:
   a) identifies potential threats,
   b) develops preventive measures, and
   c) prioritises them against the threats.
2) In order to identify the threats, the organization shall assess the susceptibility of its products to potential acts of:
   a) sabotage,
   b) vandalism, and/or
c) terrorism.

2.1.4.5.2 Preventive measures

The organization shall put in place appropriate preventive measures to protect consumer health impacts. These processes shall;

a) be controlled within the scope of the food safety management system;
   b) be in compliance with applicable legislation.

2.1.4.5.3 Annual review

1) The food defense procedure shall be reviewed:
   a) after each actual or potential failure of a preventive measure, and
   b) at least annually.
2.1.4.6 Food Fraud prevention

2.1.4.6.1 Vulnerability assessment
1) The organization shall document, establish and maintain a documented procedure for food fraud vulnerability assessment that:
   a) identifies potential vulnerabilities,
   b) develops preventive measures, and
   c) prioritises them against the vulnerabilities.
2) In order to identify the vulnerabilities, the organization shall assess the susceptibility of its products to potential acts of food fraud.

2.1.4.6.2 Preventive measures
1) The organization shall put in place appropriate preventive measures to protect consumer health. These processes shall:
   a) be controlled within the scope of the food safety management system;
   b) be in compliance with applicable legislation.

2.1.4.6.3 Annual review
2) The food fraud prevention procedure shall be reviewed;
   a) after each actual or potential failure of a preventive measure, and
   b) at least annually.

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

2.1.4.8 Management of allergens
1) A documented allergen management procedure shall be in place that includes:
   a) risk assessment identifying potential allergen cross contamination;
   b) controls to reduce or eliminate the risk of cross contact;
   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 destination.

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

2.1.4.10 Environmental monitoring
The standard shall ensure that an environmental monitoring program is in place validating and verifying the microbiological hygiene of the site demonstrating the effectiveness of cleaning and sanitation programs.
2.1.4.11 Logo use

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:

<table>
<thead>
<tr>
<th>Colour</th>
<th>PMS</th>
<th>CMYK</th>
<th>RGB</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green</td>
<td>348 U</td>
<td>82/25/76/7</td>
<td>33/132/85</td>
<td>218455</td>
</tr>
<tr>
<td>Grey</td>
<td>60% black</td>
<td>0/0/0/60</td>
<td>135/136/138</td>
<td>87888a</td>
</tr>
</tbody>
</table>

Use of the logo in black and white is permitted when all other text and images are in black and white.

In order to avoid any suggestion 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 product,
- its labelling,
- its packaging,
- in any other manner that implies FSSC 22000 approves a product, process or service.