UNDERSTANDING THE FSSC 22000 FOOD SAFETY SYSTEM CERTIFICATION STANDARD

A WHITE PAPER ON THE CHALLENGES, IMPACTS AND OPPORTUNITIES CONTAINED IN FSSC 22000

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ABSTRACT

The purpose of this document is to provide an introduction to the FSSC 22000 Food Safety System Certification standard requirements. This document is not intended to be a full explanation of the standard or of its implementation. Rather, it aims to promote understanding of the standard and its benefits to organisations doing business at a domestic or international level within the food industry.

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I. EXECUTIVE SUMMARY

Food safety is an issue that will always be on consumers’ minds. Over the years, many regional and customised food safety standards have evolved in order to enhance food safety and address the issues raised by manufacturers, suppliers, retailers and consumers.

Recently, the Global Food Safety Initiative (GFSI) fully recognised FSSC 22000 as a new food safety standard. FSSC 22000 incorporates many of the principles of other GFSI approved food safety standards. This allows organisations that achieve FSSC 22000 certification to meet the requirements of several global retailers or major branded food companies under a single, internationally recognised food safety management system.

FSSC 22000 presents one of the most comprehensive approaches to a food safety management system for those engaged in the manufacturing of food items. Because of its basis in ISO 22000:2005, the new standard seamlessly integrates into other quality management systems such as ISO 9001, ISO 14001 and OHSAS 18001, making it an integral part of any food manufacturing organisation’s ability to improve quality and ensure safety.

Ultimately, FSSC 22000 combines the benefits of a business management tool linking food safety and business processes with the ability to meet growing global customer requirements for GFSI recognised supplier food safety system certification.
II. GLOBAL FOOD SAFETY – A CHALLENGING ENVIRONMENT

Consumers are becoming more and more concerned about food safety. From tainted milk to contaminated peanut butter, food scares and recalls have been ever-present over the past several years. Extended global supply chains and lack of adequate control mechanisms are some of the key reasons. As manufacturers and retailers make efforts to address deficiencies in their supply chains, and multiple safety standards and schemes are proposed and adopted, progress is being made to ensure global food safety.

The introduction of FSSC 22000 marks a major step closer towards a single, internationally accredited and recognised superior food safety standard. It combines the ISO 22000:2005 Food Safety Management standard with the Publicly Available Specification (PAS) 220:2008 and other additional requirements. The standard has been fully recognised by the Global Food Safety Initiative (GFSI), an organisation committed to benchmarking food safety management schemes with an aim towards fostering a convergence between food safety standards. GFSI is also focused on improving cost efficiency throughout the food supply chain through the common acceptance of GFSI recognised standards by retailers around the world.

In 2001, the International Organization for Standardization (ISO) started the development of an auditable standard for the food industry, building on the Hazard Analysis and Critical Control Points (HACCP) certification’s role in food safety management systems. The result was ISO 22000:2005, issued in 2005. Its aim was to define food safety management requirements for companies that needed to comply with a wide variety of global food safety regulations.

ISO 22000:2005, however, was not approved by GFSI at the time due to weak prerequisite programme content. To bolster this content, a group of large multinational companies wrote an addendum to the ISO 22000:2005 standard, known as the Publicly Available Specification 220 (PAS 220:2008), issued in 2008.

GFSI agreed that the combination of ISO 22000:2005 and PAS 220:2008 contained adequate content for approval, but that there must exist an industry-owned scheme governing the combination of these two standards, along with emphasis on regulatory and customer requirements.

Consequently, the Foundation for Food Safety Certification developed FSSC 22000, combining ISO 22000:2005, PAS 220:2008 and some additional regulatory and customer requirements. FSSC 22000 was approved by GFSI in May 2009 as a global benchmark in food safety management. Since February 2010, FSSC 22000 became the sixth standard to join the stable of GFSI recognised schemes. This move helps drive cost efficiency and consistency in supply chains around the world when sourcing food and deliver greater confidence to the end users of third-party certification whilst providing flexibility and choice.¹

The result is an international, auditable standard that specifies the requirements for food safety management systems by incorporating all the elements of Good Manufacturing Practices (GMP) and Hazard Analysis Critical Control Points (HACCP) together with a comprehensive management system. FSSC 22000 gives organisations a way to demonstrate, in an internationally understood format, that they have a comprehensive management system that meets the food safety requirements of both customers and regulatory agencies. The standard has been designed to cover all the processes along the food chain that deal directly or indirectly with the end product being consumed. It brings everybody along the food chain under a single food safety management umbrella, making it easier to train, implement and audit the management of food safety at every level of the food chain.

¹ Source: GFSI (www.ciesnet.com)
THE ORIGINS OF A GLOBAL STANDARD

1938
Good Manufacturing Practices are enforced by the US Food and Drug Administration (FDA) as a result of 1938 Food, Drug, and Cosmetic Act.

1960s
Hazard Analysis and Critical Control Point (HACCP) principles created.

1988
First British Retail Consortium (BRC) standard introduced (now a GFSI approved standard).

Late 1990s
GlobalGAP launched (originally as EurepGAP).

May 2000
Global Food Safety Initiative (GFSI) founded. One of GFSI’s main objectives is to benchmark food safety management schemes with an aim towards convergence between food safety standards.

1995
Safe Quality Food (SQF) standard launched (a GFSI approved standard).

2004
International Food Standard (IFS) launched (a GFSI approved standard).

2004
Foundation for Food Safety Certification founded.

2005
ISO 22000:2005 issued, not approved by GFSI due to lack of sufficient prerequisite programmes.

2007
Top seven retailers agree to reduce duplication in the supply chain through the common acceptance of any of the GFSI benchmarked schemes (BRC, IFS, SQF or Dutch HACCP).

2008

2009

May 2009
Content of FSSC 22000 approved by GFSI.

Feb 2010
FSSC 22000 fully recognised by GFSI.
III. THE CORE COMPONENTS OF FSSC 22000

IN-DEPTH ON ISO 22000:2005

To fully understand the certification requirements of FSSC 22000, it is important to include an overview of ISO 22000:2005 and PAS 220:2008, since they form the basis of the standard.

ISO 22000:2005 was designed to cover all the processes along the food chain that deal directly or indirectly with the end product being consumed. Furthermore, it specifies the requirements for food safety management system by incorporating all the elements of Good Manufacturing Practices (GMP) and Hazard Analysis Critical Control Points (HACCP) together with a comprehensive management system. This standard is made up of eight core elements, detailed below.

Scope

The scope focuses on control measures to be implemented to ensure that processes are in place to meet customer and regulatory food safety requirements. The types of organisations in the food chain to which this standard can be applied are the ones that are directly or indirectly involved in one or more steps of the food chain, regardless of the size or complexity of the organisation.

Normative Reference

This refers to materials that can be used to determine definitions associated with terms and vocabulary used in the ISO standard document.

Terms & Definitions

In an effort to maintain consistency and encourage the use of common terminology, ISO 22000:2005 terms and definitions section makes reference to the use of the 82 definitions found in ISO 9001:2008 and lists definitions that are specific to this application. The rationale behind the definition section is to provide clarity of terminology and promote the use of a common language.

Food Safety Management System

In the food safety management system section, the emphasis is on establishing, documenting, implementing and maintaining an effective food safety management system. This includes procedures and records that are needed to ensure effective development, and implementing and updating of the food safety management system.

Management Responsibility

The section on management responsibility outlines the commitment of top management to the implementation and maintenance of the food safety management system. Assigning a food safety system manager and team, setting clear policies, goals, emergency contingency plans and responsibilities, along with establishment of effective communication mechanisms within the organisation and with suppliers or customers are key elements of this clause. Regularly scheduled management reviews ensure that top management is made aware of the status of the system and that actions are authorised to correct non-conformities and continually improve the food safety management system.

Resource Management

An effectively implemented food safety management system requires that top management provide adequate resources, budgets and personnel to effectively run the system. Scheduled, documented training and evaluations of key personnel and provision of a safe, work environment and infrastructure are crucial to the continuity of the system.

Planning and Realisation of Safe Products

This section incorporates the elements of Good Manufacturing Practices (GMP) and Hazard Analysis Critical Control Point (HACCP), including any regulatory requirements applicable to the organisation and processes. Adequate prerequisite programmes (e.g. training, sanitation, maintenance, traceability, supplier review, control of non-conforming product and recall procedures) are required that address general requirements to provide a foundation for the production of safe food.

Validation, Verification and Improvement of the Food Safety Management System

In order to maintain and demonstrate the effectiveness of the food safety management system, the organisation must validate that all assumptions used within the system are scientifically sound. In addition, the organisation must plan, conduct and document regular verification of all components of the system to evaluate whether or not the system is operating as designed or if modifications are needed. The verification must also form part of a continual improvement process whereby the organisation reviews verification.

A CLOSER LOOK AT PAS 220:2008

PAS 220 is equivalent to and interchangeable with ISO/TS 22002-1. Among the specific food safety requirements that ISO 22000:2005 established for organisations in the food supply chain was the need to create, implement and maintain prerequisite programmes (PRPs) to assist in eliminating food safety hazards in the manufacturing process. PAS 220:2008 supplements the prerequisite programmes in ISO 22000:2005, making it more complete and bringing it in line with the Global Food Safety Initiative (GFSI) requirements for benchmarking standards.

PAS 220:2008 specifies the exact requirements for PRPs. The specification applies to all organisations, regardless of size or complexity, as well as to all who are involved in the manufacturing step of the food chain and who wish to implement PRPs in such a way as to address the requirements specified in ISO 22000:2005.
Food manufacturing operations are diverse and not all of the requirements specified in this PAS apply across the board to all organisations. It includes detailed requirements, among which are:

- Construction and layout of buildings;
- Layout of premises and workspace;
- Utilities (air, water, energy);
- Waste disposal;
- Equipment suitability, cleaning and maintenance;
- Management of purchased materials;
- Measures for the prevention of cross contamination;
- Cleaning and sanitising;
- Pest control; and
- Personnel hygiene and employee facilities.

It also adds other aspects that are considered relevant to manufacturing operations:

- Rework;
- Product recall procedures;
- Warehousing;
- Product information/consumer awareness; and
- Food defence, biovigilance and bioterrorism.

**WHAT DOES FSSC 22000 ADD TO ISO 22000:2005 AND PAS 220:2008?**

FSSC 22000 includes additional requirements which re-emphasise the criteria already covered under the component standards with which manufacturers and suppliers must comply. These additional requirements stipulate that:

- Manufacturers should have an inventory of applicable foreign, regulatory and statutory requirements on food safety, including those that apply to: raw materials; services provided; and products manufactured and delivered. In addition, the manufacturer should comply with codes of practice related to food safety, customer requirements related to food safety and any other additional requirements on food safety determined by the customer.
- The food safety system should ensure and demonstrate conformity with these requirements.
- The manufacturer should also ensure that all services (including utilities, transport and maintenance) which may have an impact on food safety, have specified requirements, be described in documents to the extent needed to conduct hazard analysis, and be managed in conformance with the requirements of PAS 220:2008, clause 9.
- Finally, that the manufacturer should ensure the effective supervision of the personnel in the correct application of the food safety principles and practices commensurate with their activity.

**FSSC 22000 SCOPE**

FSSC 22000 can be applied to a broad swath of organisations of any size or complexity in food manufacturing. It does not matter what position the manufacturers occupy in the food chain, nor whether they are for profit or not, nor whether they are public or private companies. This includes manufacturers of:

- Perishable animal products, excluding slaughtering and pre-slaughtering, (i.e., packaged meat, poultry, eggs, dairy and fish products);
- Perishable vegetal products (i.e., packed fresh fruits and fresh juices, preserved fruits, packaged fresh vegetables, preserved vegetables),
- Products with a long shelf life (i.e., canned products, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar, salt); and
- Food ingredients, excluding technical and technological aids, (i.e., additives, vitamins and bio-cultures).
THE AUDIT PROCESS

The audit process for FSSC 22000 is based on the ISO 22000:2005 framework and runs on a three year cycle.

INITIAL AUDIT STAGE 1
Evaluation of FSMS documentation, scope, resources and preparedness for Stage 2

INITIAL AUDIT STAGE 2
Evaluation of the implementation and effectiveness of the FSMS

Closing meeting and confirmation of any non-conformities

Initial audit corrections and corrective action completed

Corrective action not completed or not satisfactory

No certificate issued

Corrective action evidence assessed by certification body by documented evidence or Revisit. Successful close out documented

Independent certification review completed

Certification decision made by certification body

Ongoing surveillance audits (see Surveillance Audits flow chart)
SURVEILLANCE AUDITS

To ensure continuous improvement, a series of surveillance audits are scheduled, with a minimum of one per year.

Following issuance of the certification, ongoing pre-planned surveillance audits occur a minimum of once per year.

A surveillance audit report is completed and detailed findings during the audit and non-conformities are documented.

Non-conformities raised:
- Correction and corrective action must be taken and verified by the auditor either by a re-visit or documented evidence.
  - No correction or corrective action taken or not effective
    - Decision taken on suspension or withdrawal of the certificate
  - Correction and corrective action acceptable
- Continuing Surveillance visits
- Re-Certification every 3 years

Minor non-conformity raised:
- Correction and corrective action plan submitted and verified. Full verification of the corrective action completed at the next due visit.
  - No correction or corrective action plan submitted
  - Decision taken on suspension or withdrawal of the certificate

No non-conformities raised:
- Correction and corrective action acceptable
- Continuing Surveillance visits
- Re-Certification every 3 years
WHY FSSC 22000 WORKS

FSSC 22000 is the most comprehensive food safety management systems standard because it:

- Integrates food safety management easily with other management systems, such as quality, environmental and safety management systems;
- Fully incorporates ISO 22000:2006, PAS 220:2008 Pre-requisite Programmes (PRPs), HACCP, and the application steps of CODEX;
- Is fully recognised by the Global Food Safety Initiative (GFSI);
- Controls/reduces food safety hazards and promotes continuous improvement on Food Safety Aspects;
- Fosters legal compliance;
- Increases transparency throughout the food supply chain; and
- Allows small and/or less developed organisations to implement an externally developed system.

In addition, FSSC 22000 incorporates many of the principles of other GFSI approved food safety standards and combines them in a single approach.

How the GFSI requirements are covered in the key global food safety standards:

<table>
<thead>
<tr>
<th>GFSI REQUIREMENTS</th>
<th>FSSC 22000</th>
<th>BRC</th>
<th>SQF</th>
<th>IFS</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOOD SAFETY MANAGEMENT SYSTEM</td>
<td>Food Safety Management System (FSMS)</td>
<td>Food Safety and Quality Management System</td>
<td>Food Safety and Quality Management System</td>
<td>Quality Management System</td>
</tr>
<tr>
<td>Management Responsibility</td>
<td>Senior Management Commitment and Continual Improvement</td>
<td>Commitment</td>
<td>Senior Management Responsibility</td>
<td></td>
</tr>
<tr>
<td>Management of Resources</td>
<td>Personnel</td>
<td>Training of Personnel</td>
<td>Resource Management</td>
<td></td>
</tr>
<tr>
<td>Planning and Realisation of Safe Products</td>
<td>Food Safety and Quality Management System, Product Control</td>
<td>Specification and Product Development</td>
<td>Production Process</td>
<td></td>
</tr>
<tr>
<td>Validation, Verification and Improvement of the FSMS</td>
<td>Internal Audit, Corrective and Preventive Action, and Calibration</td>
<td>Verification, Corrective and Preventive Action, and Calibration of Equipment</td>
<td>Measurement, Analysis and Improvement</td>
<td></td>
</tr>
<tr>
<td>GOOD MANUFACTURING PRACTICES, GOOD DISTRIBUTION PRACTICES, GOOD AGRICULTURAL PRACTICES</td>
<td>Planning and Realisation of Safe Products and PAS220</td>
<td>Site Standard, Process Control, Personnel</td>
<td>Site Security, Identify Preserved Food, Product ID, Trace and Withdraw, and Food Safety Fundamentals</td>
<td>Human Resources, Food Hygiene Requirements (clauses 4.6-4.18)</td>
</tr>
<tr>
<td>HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP)</td>
<td>Planning and Realisation of Safe Products, Validation, Verification and Improvement of the FSMS</td>
<td>Food Safety Plan – HACCP</td>
<td>Specification and Product Development, Attaining Food Safety</td>
<td>HACCP</td>
</tr>
</tbody>
</table>
Comparison of FSSC 22000, ISO 9001, ISO 14001 and OHSAS in terms of Management Systems Requirements:

<table>
<thead>
<tr>
<th>MANAGEMENT SYSTEM REQUIREMENTS</th>
<th>FSSC 22000</th>
<th>ISO 9001</th>
<th>ISO 14001</th>
<th>OHSAS 18001</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Management System</td>
<td>Clause 4</td>
<td>Clause 4</td>
<td>Clauses 4.1, 4.4.4, 4.4.5 and 4.5.4</td>
<td>Clauses 4.1, 4.4.4, 4.4.5 and 4.5.4</td>
</tr>
<tr>
<td>Management Responsibility</td>
<td>Clause 5</td>
<td>Clause 5</td>
<td>Clauses 4.1, 4.2, 4.3, 4.4.1, 4.4.3 and 4.6</td>
<td>Clauses 4.1, 4.2, 4.3, 4.4.1, 4.4.3 and 4.6</td>
</tr>
<tr>
<td>Management of Resources</td>
<td>Clause 6</td>
<td>Clause 6</td>
<td>Clauses 4.4.1 and 4.4.2</td>
<td>Clauses 4.4.1 and 4.4.2</td>
</tr>
<tr>
<td>Product Realisation and Operational Control</td>
<td>Clause 7</td>
<td>Clause 7</td>
<td>Clauses 4.3.1, 4.3.2, 4.4, 4.4.3 and 4.4.6</td>
<td>Clauses 4.3.1, 4.3.2, 4.4, 4.4.3 and 4.4.6</td>
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<tr>
<td>Measurement, Analysis and Improvement</td>
<td>Clause 8</td>
<td>Clause 8</td>
<td>Clause 4.5</td>
<td>Clause 4.5</td>
</tr>
</tbody>
</table>

MOVING TOWARDS FSSC 22000 CERTIFICATION

As the undisputed market leader in ISO 22000:2005 certifications and the pioneer of the Customised Single Food Audit Solution1, our experience leads us to believe that organisations with an existing food safety programme can incorporate the elements of FSSC 22000 into their existing system by using a stepwise approach to achieve compliance with global food safety management principles.

An organisation with any of the existing food safety programmes discussed here can build on their existing platform and seamlessly transition to FSSC 22000 certification. The FSSC 22000 scheme, through its inclusion of ISO 22000:2005 and PAS 220:2008 standards, covers key requirements contained in major existing food safety standards or programmes, including: GMP, HACCP, SQF, BRC, IFS and GlobalGAP.

V. CONCLUSION

FSSC 22000 combines the benefits of a business management tool linking food safety and business processes with the ability to meet growing global customer requirements for a GFSI recognised supplier food safety system certification. FSSC 22000 stipulates measurable senior management commitment and requires organisations to analyse customer requirements, define processes and demonstrate consistent control over identified hazards, updating and improving the system to adapt to changes in process, requirements or regulations. It provides real value to an organisation irrespective of size or complexity and levels the playing field for suppliers and buyers throughout the food chain and around the world.

1 The Customised Single Food Audit solution combines the parallel requirements of major international standards (such as ISO 9001:2008, ISO 14001, OHSAS 18001, FSSC 22000, GMP, ISO 22000:2005, PAS 220:2008 HACCP, SQF, IFS and BRC) and covers them cost-effectively with a single audit, saving companies audit time and making it more effective for companies to manage multiple certifications.
ABOUT THE AUTHORS

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Supreeya Sansawat has over 17 years of experience in quality assurance in the food industry including auditing and training. Supreeya has auditing experience in many food safety schemes, including GMP, Dutch HACCP, SQF, ISO 22000, ISO 9001, BRC and GlobalGAP and has performed over 1,000 audits. She is now responsible for all of the technical development for our food safety solutions, including maintaining and improving food safety auditor and trainer competencies for all GFSI recognised schemes as well as other standards related to the food industry.

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Victor Muliyil is an accredited multi-sector food safety programme lead auditor and trainer for BRC, SQF 1000/2000, GMP/HACCP, ISO 22000 and ISO 9001. Victor is also responsible for the development and upgrading of food safety training courses, food safety and quality audit procedures and risk management programmes for several North American clients. He has over 22 years of experience in analytical laboratory management, quality assurance, food safety system development, implementation and auditing and holds degrees in Biochemistry, Microbiology and Food Science from the University of Toronto.

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