

Comparison of GFSI Guidance Document 4th Edition (July 2004) and GFSI Guidance Document 5th Edition (September 2007)

Overview

The GFSI Guidance Document 5th Edition was published in September 2007. The document replaced the 4th Edition of the GFSI Guidance Document that was issued in July 2004. The Guidance Document sets out the key elements for production of food as requirements for food safety management schemes and gives guidance to schemes seeking compliance with it. It is a framework in which food safety management schemes can be benchmarked.

This comparison document will allow a detailed review of the differences between the Guidance Documents to be made by the reader and also will serve as a record for the GFSI as a reference document in its own right.

Format of Comparison Table

The table below has been developed to provide a direct comparison of the documents and where major changes have been made, the text is highlighted in bold format.

Summary of Major Changes

The major changes can be summarised as follows;

- there is a clear definition of GFSI as a legal entity
- provides confirmation of the GFSI mission and objectives
- confirms the requirement for recognised schemes to be open and transparent
- has extended the requirement of the recognised schemes to be reviewed and updated from at least every three years to at least every five years
- clearly defines and describes the revised Benchmarking process
- there have been a number of amendments and changes to specific requirements of the schemes e.g. specification review, batch traceability requirements and serious incident management
- there have been significant changes to the requirements relating to auditor competence
- there is a defined audit frequency of a minimum of 12 months
- defines and address conflict of interest for certification bodies and auditors

GFSI 4 th Edition	Revision	GFSI 5 th Edition	Revised Statement
Foreword	Additional information about GFSI	Foreword	Additional wording added- The Global Food Safety Initiative (GFSI) is a non-profit making foundation, created under Belgian law. The daily management is undertaken by CIES – The Food Business Forum.
Contents	Revised Part III No 7	Contents	<p>7. Requirements for the delivery of food safety management systems</p> <p>Introduction Guidance for the management of certification bodies Frequency/Duration of Audit Food certification – categories Auditor qualifications, training, experience and competencies Conflict of Interest Minimum requirements for audit reports Evaluation Corrective Action of Non Conformities Certification Decision Distribution of Audit Reports</p>
Contents	Additional Annexes	Contents	<p>Part 1 Annex 1 Blank Benchmark Matrix for Scheme Owners Part 1 Annex 2 Cross Reference List for Scheme Owners Part II Annex 1 Key Elements: Good Manufacturing Practices, Good Agricultural Practices, Good Distribution Practices</p>

**Part I
Requirements
for Food Safety
Schemes
1 Introduction**

Revised to provide more information about GFSI
Confirmation of the GFSI Mission
Confirmation of GFSI Objectives
Information about the GFSI Technical Committee

Part I
Requirements
for Food Safety
Schemes
1 Introduction

The Global Food Safety Initiative (**GFSI**) coordinated by CIES - The Food Business Forum, was launched in May 2000. The GFSI Foundation Board, a retailer-driven group, with manufacturer advisory members, provides the strategic direction and oversees the daily management of the Global Food Safety Initiative. Membership of the Board is by invitation only.

The **GFSI Mission** is to work on continuous improvement in food safety management systems to ensure confidence in the delivery of food to consumers.

The **GFSI Objectives** are to:

- Maintain a benchmarking process for food safety management schemes to work towards convergence between food safety standards, as outlines in this Guidance Document.
- Improve cost efficiency throughout the food supply chain through the common acceptance fo GFSI recognised standards by retailers around the world.
- Provide a unique international stakeholder platform for networking, knowledge exchange and sharing of best food safety practice and information.

The GFSI Foundation Board also provides governance to the Technical Committee, an international multi-stakeholder group of over 50 food safety experts. The Technical Committee is

open to all retailers and to other members by invitation only. The Technical Committee works on specific selected projects throughout the year, approved by the GFSI Foundation Board in order to fulfil the GFSI Mission.

2 Scope

Revised 1st, 3rd and 4th Paragraphs to explain benchmarking and clarity
Omission of the statement - **GFSI will produce an annual report**

2 Scope

1st Para-

The Guidance Document sets out the key elements for production of food as requirements for food safety management schemes and gives guidance to schemes seeking compliance with it. It is a framework in which food safety management schemes can be benchmarked. The **GFSI** Guidance Document, therefore, is not a standard in itself and **GFSI** is not involved in certification or accreditation activities.

3rd Para-

The conforming food safety management schemes can be applied by food suppliers throughout the supply chain. It is at the discretion of retailers and suppliers as to which products the schemes will be applied to. This will differ depending on company policy, general regulatory requirements, due diligence obligations and product liability.

4th Para

GFSI is responsible for the production and maintenance of this Guidance Document. New editions of the document will be produced at least every 5 years, although addenda may be added. Stakeholders are invited to submit comments and proposals for changes. Drafts of new editions will

3 Definitions	Addition of Conflict of Interest Definition Revised terminology of some processed food	3 Definitions	be circulated among stakeholders. Conflict of Interest Where either a Certification Body or any Auditor are in a position of trust requiring them to exercise judgement on behalf of others and also has interests or obligations (whether financial or otherwise) of the sort that might interfere with their exercise of judgement. Processed Food Additional -Steam sterilisation
4 Overview of the GFSI Guidance Document Part II	Additional information provided as part of section 'Elaboration of Key Elements'	4 Overview of the GFSI Guidance Document Part II	The Key Elements structure has been developed by GFSI with the assistance of retailers, manufacturers and other relevant stakeholders. These Key Elements will be periodically reviewed in the light of new scientific knowledge to ensure continuous improvement.
4 Overview of the GFSI Guidance Document Part III	Additional information	4 Overview of the GFSI Guidance Document Part III	The requirements for the delivery of Food Certification Systems are found in Part III. Any food safety management scheme also needs to comply with these.
4 Overview of the GFSI Guidance Document Part III	Remove the last sentence from this section <i>The Key Elements structure has been developed by GFSI with the assistance of retailers, manufacturers and other relevant stakeholders. These Key Elements will be periodically reviewed in the light of new scientific knowledge so as to ensure a regime of continuous improvement.</i>		
5 Procedures for the	Wording revised The requirements contained in this chapter are	5 Procedures for the	The requirements contained in this chapter are intended to provide confidence in the compliance

application and benchmark of food safety management schemes	written, above all, to provide reliability and confidence in the compliance of a specified standard and its related certification system to the GFSI Guidance Document.	application and benchmark of food safety management schemes	of a specific standard and its related certification system to the GFSI Guidance Document.
5.1 Introduction		5.1 Introduction	
5.2 Scope	Revised The main requirement is that the conforming scheme shall be publicly available in all cases, and its use for certification purposes, without restriction by membership or other limitation, to certification bodies (see clause 5.7.3).	5.2 Scope	The main requirement is that the scheme shall be publicly available in all cases and its use for certification purposes be open , without restriction by membership or other limitation, to certification bodies (see clause 5.7.3).
5.3 References	Revised <ul style="list-style-type: none"> • ISO 19011 Guidelines for quality and/or environmental management systems auditing • ISO/IEC Guide 7 – 1994 Guidelines for drafting standards suitable for use of conformity assessments • ISO/IEC Guide 65 – 1996 General requirements for bodies operating product certification systems • ISO/IEC Guide 2– 1996 General terms and their definitions concerning standardization and related activities 	5.3 References	<ul style="list-style-type: none"> • ISO 19011:2002 Guidelines for quality and/or environmental systems auditing. • ISO/IEC Guide 7:1994 Guidelines for drafting standards suitable for use of conformity assessments. • ISO/IEC Guide 65:1996 General requirements for bodies operating product certification systems (status is “international standard to be revised” but it is still current at the moment). • ISO/IEC Guide 2:2004 Standardisation and related activities – General vocabulary. • ISO 9000:2005 Quality Management Standards – fundamentals & vocabulary.

- ISO 8402- 1994 Quality management and quality assurance – vocabulary

5.4 Conforming certification system	Change in section title	5.4 Certification system	
5.5.2.2	Clause removed GFSI will maintain in its Guidance Document requirements as set out in ISO/IEC Guide 65 clause 5.2 for certification body personnel qualification criteria and clause 13 for surveillance.	5.5.2.2	Moved to 5.5.2.2 GFSI will ensure that clear, unambiguous and objective guidance is given on interpretation of the GFSI Guidance Document.
5.7 Benchmark Procedure	Revised GFSI will operate the following procedures to ascertain whether a standard and its certification system can demonstrate compliance with the GFSI Guidance Document. GFSI will ensure that the Benchmark Procedure is implemented under independent, impartial, technically competent and transparent procedures.	5.7 Benchmark Procedure	GFSI will operate the following procedures to ascertain whether a standard and its certification system can demonstrate conformity against the Guidance Document. In addition, GFSI will ensure that the Benchmark Procedure is implemented in an independent, impartial, technically competent and transparent manner.
5.7.2.1		5.7.2.1	ADDITIONAL CLAUSE (d) If during the course of this cross referencing exercise the scheme owner identifies obvious areas of non-compliance with the Guidance Document, these must be addressed prior to submission of the scheme for benchmarking.
5.7.3	Revision to points b) and d) (b) be reviewed and updated, at least every three years, with the involvement of representatives of direct stakeholders (see clause 5.11	5.7.3	(b) be reviewed and updated, at least every five years, with the involvement of representatives of direct stakeholders (see clause 5.11)

(d) be clear and precise in its wording and phraseology to facilitate accurate and uniform interpretation, and allow for the evaluation of compliance of an applicant. Terms such as “sufficient” and “adequate” should be avoided

(d) be clear and precise in its wording and phraseology to facilitate accurate and uniform interpretation and allow for the evaluation of compliance of an applicant. Terms such as “sufficient” and “adequate” should be avoided **wherever possible**

5.7.4 Technical Review

Change in section title and revised wording
GFSI will appoint a Technical Review Committee, made up of suitable technical persons from within or outside the **GFSI** Task Force that are independent, impartial and technically competent persons or organisations with no direct connections with a certification body or a scheme owner, which will complete a preliminary screening to ensure that the application meets all the requirements as defined by **GFSI**. These technical persons must have experience in conformity assessment, and shall have a minimum of five years experience relevant to the food industry (this shall involve work in quality assurance or food safety functions within manufacture, retailing, inspection or enforcement).

5.7.4 Benchmarking Committee

GFSI will appoint by invitation a Benchmarking Committee, made up of suitably qualified persons or organisations that are independent, impartial and technically competent from retailers, manufacturers and other appropriate experts. The committee will complete a preliminary screening to ensure that the application meets all requirements defined by **GFSI**. The committee members must have experience in conformity assessment and shall have a minimum of five years experience relevant to the food industry (this shall involve work in quality assurance or food safety functions within manufacture, retailing, inspection or enforcement).

If the application is accepted, the submitted application will be reviewed in detail. This independent Technical Review will include a written consultation with the Task Force and stakeholders including primary producers, manufacturers, wholesaler distributors, and representatives of accreditation bodies and certification bodies

If the preliminary screening is successful, the submitted application will be reviewed in detail. This independent review will include a written consultation with the Benchmarking Committee. If needed, an explanatory meeting with the

operating the submitted scheme. If needed, an explanatory meeting with the applicant can also be organised.

This independent review will summarise all the consultation responses, the application itself and produce a detailed report with one of the following recommendations:

- (i) compliance is accepted
- (ii) compliance is not accepted until modifications recommended by the Technical Review Committee have been made by the scheme owner
- (iii) rejection of the application.

In the case of acceptance after modifications the scheme owner should provide the Technical Review Committee with a written justification on how to implement the modifications in the existing scheme within a mutually accepted time frame. In cases where the conforming scheme is already in use, the scheme owner should also provide information as to how the modifications will be implemented at already certified suppliers.

GFSI, through its Advisory Group, will review the Independent Technical Review Report and will decide to accept, accept after modifications or reject the application. Written justification must be provided if the Advisory Group does not accept the recommendations or in case of dispute.

applicant can also be organised. The Benchmarking Committee will summarise all the consultation responses and the application itself and produce a detailed report with one of the following recommendations:

- (i) compliance is accepted
- (ii) compliance is not accepted until modifications recommended by the Benchmarking Committee have been made by the scheme owner
- (iii) rejection of the application.

In the case of acceptance after modification, the scheme owner should provide the Benchmarking Committee with a written proposal on implementation of the modifications in the existing scheme within a mutually accepted time frame. In cases where the conforming scheme is already in use, the scheme owner should also provide a proposal on implementation of the modifications at suppliers already certified.

The **GFSI Board** will review the recommendation and will decide to accept, accept after modifications or to reject the application. Written justification must be provided if the GFSI Board does not accept the recommendation or in case of dispute.

<p>5.7.5 Compliance statement</p>	<p>Revised If the Advisory Group decides positively, a compliance statement will be issued. Written</p>	<p>5.7.5 Compliance statement</p>	<p>If the food safety management scheme is in compliance, a compliance statement will be issued. If not, the applicant will in any event, be</p>
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	<p>procedures will be in place to notify applicants of the outcome of the benchmark process. The time period to complete this process from application to decision should not be any more than three months after the date of submission. The compliance statement should be publicly available and clearly indicate:</p> <ul style="list-style-type: none"> a) The GFSI Guidance Document and its edition number b) The conforming scheme including all normative documents involved with their revision number or date. 		<p>informed in writing of the outcome of the benchmarking process. The time period to complete this process from application to final decision should not be any more than three months from the date of submission. The compliance statement should be publicly available and clearly indicate:</p> <ul style="list-style-type: none"> a) The GFSI Guidance Document and its edition number b) The conforming scheme, including all normative documents involved, with their revision number or date.
<p>5.7.6 Contractual arrangements</p>	<p>Removed</p>		
<p>5.9 Transparency</p>	<p>Revised wording The operation of all procedures in connection with the benchmark will be conducted in a transparent way and all documents will be available to applicants, stakeholders and GFSI at the end of the procedure in case of a compliance statement.</p> <p>In the circumstance that an application is not successful, this will only take place in a direct communication with the applicant only.</p>	<p>5.9 Transparency</p>	<p>All procedures involved in the benchmark will be transparent. All documents will be made available to applicants, stakeholders and GFSI at the end of the process in the case of a compliance statement being issued.</p> <p>If an application is not successful, there will be direct communication with the applicant only and documents will not be made generally available.</p>

<p>5.11 Review and updates to the GFSI Guidance Document and benchmarked schemes</p>	<p>Revised</p> <p>All changes to a conforming scheme require re-submission to GFSI. After re-submission, the procedure described in clauses 5.7.4 and 5.7.5 will be followed again. If anomalies are found, the scheme owner needs to implement the modifications in the existing scheme within a mutually accepted time frame of no more than one year, to maintain the compliance status of the scheme.</p> <p>A conforming scheme owner shall update his conforming scheme in line with updates incorporated into the GFSI Guidance Document within one year of the publication thereof, to maintain the compliance status of the scheme.</p> <p>GFSI will have systems in place to ensure that the status of the conforming schemes is reviewed not less than every 3 years.</p>	<p>5.11 Review and updates to the GFSI Guidance Document and benchmarked schemes</p>	<p>Any changes to the conforming scheme which could result in non-conformity with the Guidance Document, should be promptly communicated to GFSI. The amended scheme should be re-submitted to GFSI, following the procedure described in clauses 5.7.4 and 5.7.5. If anomalies are found, the scheme owner shall implement the modifications in the existing scheme within a mutually accepted time frame, not exceeding 1 year, in order to maintain the compliant status of the scheme.</p> <p>Following publication of a new version of the Guidance Document, GFSI will conduct a preliminary benchmark exercise against the current version of conforming Standards. Standard Owners will be advised of any anomalies against the new version. In order to maintain compliant status against the new version, Standard Owners must address these anomalies within 1 year of receiving such advice.</p>
<p>5.12 Review of the delivery of conforming schemes</p>	<p>Revised</p> <p>GFSI shall require conforming standard owners to submit an annual report on the delivery of their food safety management system.</p>	<p>5.12 Review of the delivery of conforming schemes</p>	<p>GFSI will request standard owners with conforming schemes to submit an annual report on the performance of their food safety management system and to provide to GFSI any new documents having a material impact on the performance of the scheme.</p>
		<p>5.13 GFSI Logo</p>	<p>ADDITIONAL CLAUSE</p> <p>The GFSI logo should not be used by any standard owner on product labelling or as part of certification documentation without the prior written agreement of the GFSI.</p>
<p>6.0</p>	<p>Revised wording</p>	<p>6.0</p>	<p>Any food safety management standard shall be in</p>

Requirements for a conforming food safety management standard (Key Elements)	Any food safety management standard shall be in compliance with all requirements of this chapter, as appropriate with either Good Agricultural Practices, Good Manufacturing Practices or Good Distribution Practices.	Requirements for a conforming food safety management standard (Key Elements)	compliance with all requirements of this section.
6.1.1 General Requirements	Revised The conforming standard (hereafter the standard) shall require that the elements of the supplier's Food Safety Management System be documented, implemented, maintained and continually improved. The food safety management system shall:	6.1.1 General Requirements	The conforming standard (hereafter the standard) shall require that the elements of the supplier's Food Safety Management System be documented, implemented, maintained and continually improved. The food safety management system should :
6.1.6 Management Review	Revised The standard shall require that the supplier's senior management will review the verification of the food safety management system and HACCP Plan, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. Such a review shall evaluate the need for changes to the supplier's food safety management system, including the food safety policy and food safety objectives.	6.1.6 Management Review	The standard shall require that the supplier's senior management will review the verification of the food safety management system and HACCP Plan, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The HACCP Plan shall also be reviewed in the event of any change which impacts on the safety of the product. Such a review shall evaluate the need for changes to the supplier's food safety management system, including the food safety policy and food safety objectives
6.1.8 General Documentation Requirements	Revised The standard shall require that the supplier prepare documented procedures to demonstrate compliance with the specified standard and will ensure that all records required to demonstrate the effective operation and control of its processes and its management of product safety, are securely stored, effectively controlled, and readily accessible when needed.	6.1.8 General Documentation Requirements	The standard shall require that the supplier prepare documented procedures to demonstrate compliance with the specified standard and will ensure that all records required to demonstrate the effective operation and control of its processes and its management of product safety, are securely stored for a time period required to meet customer or legal requirements , effectively controlled and readily accessible when needed.

6.1.9 Specifications	Revised The standard shall require that the supplier ensure that for all items and services purchased/provided and having effect on product safety, documented specifications are prepared, securely stored and readily accessible when needed.	6.1.9 Specifications	The standard shall require that the supplier ensure that for all items and services (including utilities, transport and maintenance) purchased/provided and having effect on product safety, documented specifications are prepared, securely stored and readily accessible when needed. The standard shall require that a specification review process is in place.
6.1.17 Traceability	Revised The standard shall require that the supplier develop and maintain appropriate procedures and systems to ensure: <ul style="list-style-type: none"> • Identification in any case through a code marking on container and product, to identify the source of any out-sourced product, ingredient or service; • Record of purchaser and delivery destination for all product supplied. 	6.1.17 Traceability	The standard shall require that the supplier develop and maintain appropriate procedures and systems to ensure: <ul style="list-style-type: none"> • Identification of any out-sourced product, ingredient or service; • Complete records of batches of in-process or final product and packaging throughout the production process. • Record of purchaser and delivery destination for all product supplied.
6.1.18 Complaint Handling	Revised The standard shall require that the supplier prepare and implement an effective system for the management of complaints and the use thereof to control and correct evidence of shortcomings in food safety.	6.1.18 Complaint Handling	The standard shall require that the supplier prepare and implement an effective system for the management of complaints and complaint data to control and correct shortcomings in food safety.
6.1.19 Product Recall	Retitled and revised The standard shall require that the supplier prepare and implement an effective product recall procedure for all products it supplies, which is tested regularly.	6.1.19 Serious Incident Management	The standard shall require that the supplier prepare and implement an effective incident management procedure for all products it supplies, which is tested regularly. This should cover planning for product withdrawal and product recall.

6.1.20 Control of Measuring and monitoring Devices	Revised The standard shall require that the supplier identify the measurements critical to food safety and the measuring and monitoring devices required to assure product safety and methods to assure calibration and accuracy.	6.1.20 Control of Measuring and monitoring Devices	The standard shall require that the supplier identify the measurements critical to food safety, the measuring and monitoring devices required to assure product safety and methods to assure calibration traceable to a recognised standard.
6.1.21 Product Analysis	Revised The standard shall require that the supplier prepare and implement a system to ensure that product/ingredient analyses critical to the confirmation of product safety is undertaken and required and that such analyses conforms to publicly recognised standards.	6.1.21 Product Analysis	The standard shall require that the supplier prepare and implement a system to ensure that product/ingredient analyses critical to the confirmation of product safety is undertaken and that such analyses are performed to standards equivalent to ISO 17025.
6.2.1 Introduction	Revised This clause sets out the requirements of good practice with the goal of ensuring food safety in agriculture (Good Agricultural Practices, hereafter GAP), manufacturing (Good Manufacturing Practices, hereafter, GMP) and distribution (Good Distribution Practices, hereafter GDP). An example of more detailed requirements can be found in Part II, Annex 1. The standard shall include consideration of the following items in relation to GAP/GMP/GDP where appropriate.	6.2.1 Introduction	This clause sets out the requirements of good practice with the goal of ensuring food safety in manufacturing (Good Manufacturing Practices, hereafter, GMP). More detailed examples can be found in Part II, Annex 1. The standard shall include consideration of the following items in relation to GMP where appropriate.
6.2.2 Facility	Revised	6.2.2 Facility	The site or facility shall be located and maintained

Environment	The site or facility shall be located and maintained so as to prevent contamination and enable the production of safe (primary) products (GAP/GMP/GDP).	Environment	so as to prevent contamination and enable the production of safe products.
6.2.9 Physical and chemical Product Contamination Risk	Revised Appropriate facilities and procedures shall be in place to control the risk of physical, chemical, or biological contamination of (primary) product (GAP/GMP/GDP).	6.2.9 Physical and chemical Product Contamination Risk	Appropriate facilities and procedures shall be in place to control the risk of physical, chemical, or biological contamination of product. Appropriate controls should be in place to minimise incidence of foreign bodies, e.g. by the use of metal detection or x-ray devices.
6.2.10 Segregation and Cross-contamination	Revised Procedures shall be in place to prevent contamination and cross-contamination of raw materials, packaging and finished product (GAP/GMP/GDP).	6.2.10 Segregation and Cross-contamination	Procedures shall be in place to prevent contamination and cross-contamination of raw materials, packaging and finished product, covering all aspects of food safety including micro-organisms, chemicals and allergens.
6.2.13 Water Quality Management	Revised The quality of water that comes into contact with food, shall be regularly monitored and shall present no risk to product safety (GAP/GMP): Extra GAP: Water for post harvest washing shall be potable. Extra GMP: Potable water shall be used and checked for contaminants at an appropriate frequency.	6.2.13 Water Quality Management	The quality of water that comes into contact with food, shall be regularly monitored and shall present no risk to product safety. Water for post harvest washing shall be potable. Potable water shall be used and checked for contaminants at an appropriate frequency.
6.2.16 Veterinary Medicines	Designated as GAP only		
6.2.17 Pesticide, herbicide and	Designated as GAP only		

Fungicide Control			
6.2.18 Transport	Revised All vehicles used for the transportation of raw materials (including packaging), intermediate/semi processed (primary) product and finished (primary) product shall be suitable for the purpose, maintained in good repair and be clean (GDP).	6.2.18 Transport	All vehicles, including contracted out vehicles, used for the transportation of raw materials (including packaging), intermediate/semi processed product and finished product shall be suitable for the purpose, maintained in good repair and be clean.
6.3 Key Element Hazard Analysis and Critical Control Point (HACCP)	Revised additional information The submitted standard requires a Hazard Analysis and Critical Control Point (hereafter, HACCP) system, or equivalent, to demonstrate food safety management. The described HACCP system shall be systematic, comprehensive and thorough and shall be based on or be equivalent to the Codex Alimentarius HACCP principles or the ones from the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). The hazard analysis, where appropriate, shall include allergens. The 7 HACCP-principles shall apply to all suppliers. <i>Any supplier who is not a primary producer shall additionally comply with the guidelines for its application in formulating its HACCP plan in reference with these guidelines.</i> The scope of the HACCP-system shall be required to be defined per product, per process line/or process-location and the position within the food chain. The supplier's HACCP-system shall be able to demonstrate management commitment and shall be supported through the supplier's food safety management system.	6.3 Key Element Hazard Analysis and Critical Control Point (HACCP)	The submitted standard requires a Hazard Analysis and Critical Control Point (hereafter, HACCP) system, or equivalent, to demonstrate food safety management. The described HACCP system shall be systematic, comprehensive and thorough and shall be based on or be equivalent to the Codex Alimentarius HACCP principles or the ones from the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). The hazard analysis, where appropriate, shall include allergens. The 7 HACCP-principles shall apply to all suppliers. The scope of the HACCP-system shall be required to be defined per product, per process line/or process-location and the position within the food chain. The supplier's HACCP-system shall be able to demonstrate management commitment and shall be supported through the supplier's food safety management system. In certain cases, in particular in food businesses

Note: The principles of the HACCP system as adopted by the Codex Alimentarius Commission and guidelines for its application can be found in Codex Alimentarius as an Annex to CAC/RCP 1-1969.

where there is no preparation, manufacturing or processing of food, it may seem that all hazards can be controlled through the implementation of the prerequisite requirements. In these cases it can be considered that the first step of the HACCP procedures (hazard analysis) has been performed and that there is no further need to develop and implement the other HACCP principles.

Note: The principles of the HACCP system as adopted by the Codex Alimentarius Commission and guidelines for its application can be found in Codex Alimentarius as an Annex to CAC/RCP 1-1969.

In all cases, HACCP or Risk Assessment must be in compliance with applicable legal requirements

**PART III
Requirements
for the delivery
of food safety
management
systems**

THIS PART HAS BEEN COMPLETELY RENUMBERED
The following sections relate to the subject matter of Guidance Document Version 4 which may have been revised in Guidance Document Version 5

**7.2 Auditor
Qualification,
training and
experience**

Revised

**7.5 Auditor
Qualifications,
Training,
Experience
and
Competencies**

The Certification Body must have systems and procedures in place to ensure that auditors conducting assessment meet the capabilities described in ISO 19001 and ISO 22003 with specific regard to audits against GFSI Approved Standards.

Qualifications

The auditor shall have the minimum personal attributes, knowledge and skills and education as

**7.5.1
Qualification/
Education**

A degree in a food related or bioscience discipline, or as a minimum, have successfully completed a food related or bioscience higher

described in chapter 7 of ISO 19011, for as far as relevant for food safety management.

education course or equivalent. Auditors currently conducting audits against GFSI Approved Standards are not required to meet these qualifications provided they can demonstrate competence in the role.

Training

The auditor shall have successfully completed a Quality Management Systems lead assessor course or recognised equivalent and have undergone a supervised period of training in practical evaluation. He or she shall also have successfully completed training in HACCP based on the principles from Codex Alimentarius (Alinorm 97/13) or from the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and be able to demonstrate competence in the understanding and application of HACCP principles.

7.5.3

7.5.4

Note: The training course should be recognised by the industry (and its stakeholders) as being appropriate and relevant. For example, approval or certification by an independent body with the relevant expertise can provide some assurance that a course meets specified criteria.

Formal Auditor Training

- Auditors shall have successfully completed recognised training in auditing techniques based on QMS or FSMS – duration: 1 week/40h, or equivalent.
- Successfully completed a training course in HACCP based on the principles from Codex Alimentarius and demonstrate competence in the understanding and application of HACCP principles – minimum duration: 2 days, or equivalent.
- Successfully completed training in the Standard being delivered to the satisfaction of the Standard Owners.

Initial Training

A training programme for each auditor will incorporate:

- an assessment of knowledge and skills for each field and sub field and assignment of fields of evaluation,
- an assessment of knowledge of food safety, HACCP, Pre-Requisite Programmes and have access to, and be able to apply relevant laws and regulations,
- a period of supervised training to cover the assessment of quality management systems and HACCP, specific audit techniques and specific category knowledge,
- a documented sign off of the satisfactory

completion of the training programme by the appointed supervisor.

Experience

7.5.2

The auditor shall have a minimum of five years experience relevant to the food industry, or two years when auditing against farm assurance standards. This should involve work in Quality Assurance or food safety functions within food production or manufacturing, retailing, inspection or enforcement.

An auditor shall perform a minimum of five relevant audits per year to maintain his qualification.

Total Work Experience

5 years full time experience in the food industry including at least 2 years work in areas such as quality assurance or food safety functions within food production or manufacturing, retailing, inspection or enforcement or the equivalent.

This may be reduced to a total of 2 years experience if the competence of the auditor is assessed by an examination designed and delivered by the Standard Owner.

The examination content should as a minimum cover :

- General Knowledge of the scheme
- Knowledge of relevant legislative requirements
- Knowledge and understanding of specific food processes
- Understanding of quality assurance ,quality management and HACCP principles

Training and experience for specific categories

7.5.4

Certification bodies shall be able to demonstrate that every auditor has appropriate training and experience for the particular categories for which they are considered competent. Competence shall

7.5.5

Initial Training

A training programme for each auditor will incorporate:

- an assessment of knowledge and skills for each field and sub field and assignment of fields of evaluation,

	<p>be recorded (clause 5.5.c of ISO 19011) at least at the level of each category as indicated in chapter 7.5.</p> <p>It is difficult to be prescriptive as to the specific training required in the absence of nationally recognised training modules. Necessary training and experience shall be judged on the risk and the particular technical demands of the category.</p>		<p>Extension of Scope In order to extend scope, an auditor must undergo a programme of theoretical training in the new category, conduct supervised audits and must be assessed and signed off as competent by the Certification Body to audit in the new category.</p>
7.3 List of minimum requirements for audit reports	Revised to include Date of previous audit and name of Certification Body conducting audit	7.7 Minimum Requirements for Audit Reports	Add Date of previous audit and name of Certification Body conducting audit
7.4 Guidance for the management of certification bodies	Revised numbering of section revision to text The general requirements for accreditation are laid down in the International Standard ISO/IEC Guide 65 – General requirements for bodies operating product certification systems. These requirements apply to all types of certification and therefore need to be interpreted in respect of food safety requirements and the categories of food technology concerned	7.2 Guidance for the management of certification bodies	The Certification Body must have systems and procedures in place to ensure that auditors conducting assessment meet the capabilities described in ISO 19001 and ISO 22003 with specific regard to audits against GFSI Approved Standards.
7.4.1 Accreditation	Revised numbering of section and deletion of text Food safety management systems seeking compliance with this document must ensure that all activities resulting in the issuing of certificates are delivered by Certification Bodies, which are accredited by members of the IAF, in compliance with ISO/IEC Guide 65. <i>Standard owners shall</i>	7.2.1 Accreditation	Food safety management systems seeking compliance with this document must ensure that all activities resulting in the issuing of certificates are delivered by Certification Bodies, which are accredited by members of the IAF, in compliance with ISO/IEC Guide 65.

actively engage with the Accreditation Bodies to monitor and verify that accreditation is consistent.

7.4.2 Scope of accreditation	Revised to include an additional requirement in the first paragraph	7.2.2 Scope of accreditation	The scope of accreditation shall be precisely defined in terms of the category of application and reference to the relevant standard(s) of the conforming food safety management scheme including revision numbers and/or dates. Certification Bodies undertaking audits against food safety management schemes, which have been found to be in compliance with this document, must have the named scheme included in their scope of accreditation. In the event that any non conformity is raised by an Accreditation Body, the Certification Body must take appropriate and timely action to satisfactorily resolve the issue.
7.5 Food certification - categories	Revised text but no change to product categories. Categories have been identified as listed below, in which raw meat and fish have been divided into sub-categories. Organisations applying for accreditation or extensions of scope should use these categories in their applications.	7.4 Food certification - categories	Categories have been identified as listed below. Organisations applying for accreditation or extensions of scope should use these categories in their applications. It is, however, recognised that new food categories could emerge as Standards are developed in, for example, the Far East. If such food products do not fit easily with these categories, the new categories must be clearly defined.
7.6 Management		7.3 Duration and Frequency	

<p>of the food certification system</p> <p>7.6.1 Initial Visits</p>	<p>Revised into one new section in Guidance Document 5</p> <p>Initial visits</p> <p>The duration of an initial visit has to be determined by the certification body with due regard to:</p> <ul style="list-style-type: none"> The type of process used to manufacture the product; The conditions under which the product is stored and sold; The method of preparation of the food by the consumer; The number of sites and products; The number of employees related to food safety <p>During the initial visit it should be determined whether activities and related results comply with the standard of a conforming scheme. Therefore all the elements of such standard should be covered by reviewing the supplier's manual and related procedures, together with an inspection of the production facilities. The initial visit should be executed in two phases, where phase one contains the document review and an inspection of the premises and the production facilities, and phase two contains the evaluation of the actual implementation.</p>	<p>of Audit</p> <p>7.3.1</p>	<p>The Certification Body must define as accurately as possible the duration of the audit which should be established by information provided by the supplier on the size and complexity of the operation and the scope of the audit. The Standard Owner must clearly state the basis for determining audit duration.</p> <p>During an initial visit, this defined duration will be reviewed</p> <p>Although audit duration will vary according to this risk assessment, a minimum of 1 ½ days should be allowed for the audit. The duration of an audit may vary due to a number of factors such as audit history, severity, type and number of non conformities found, modifications to the process that drive a HACCP change, significant capacity increase, structural change or change in company management.</p> <p>All sections of the standard shall be covered by reviewing the suppliers manual and related procedures, together with an inspection of the production facilities.</p>
<p>7.6.2 Surveillance Visits</p>	<p>Covered by 7.3.1 Guidance Document 5</p>		
<p>7.6.3 Audit frequency</p>	<p>Revised and covered by 7.3.2 Guidance Document 5</p> <p>Frequency of audits shall be clearly defined. A risk-</p>	<p>7.3.2</p>	<p>The Certification Body must define the frequency of audit for each site and must clearly define the rationale for the determination of frequency within</p>

	based approach based on performance can be used.		the scheme. Audit frequency will be at a minimum of 12 months. The frequency of audit may be influenced by a number of factors such as previous audit history, seasonality of product, significant capacity increase, structural change, change in product technology or change in product type. Some limited flexibility may also be required to allow effective auditing of seasonal products. However, in this case, suppliers should be audited during every season.
7.6.4 Legality	Removed The scheme owner shall have legal advice available on all matters associated with liability and competition issues.		
7.6.5 Relationship with certification bodies	Removed As indicated in clause 5.7.3(f), the scheme owner shall operate a system, which allows free access to the certification market for companies, which can satisfy all technical requirements.		
7.6.6 Standard governance	Removed The scheme owner shall ensure that governance of the scheme is a formal process, which allows direct stakeholders to participate as advisors.		
7.6.7 Auditor competence	Revised Requirements for auditors shall be clearly defined. This GFSI Guidance Document sets out minimum qualifications in chapter 7.2. The scheme owner will identify the management processes, which will enable the identification in auditor performance by sector.	7.5	The Certification Body must have systems and procedures in place to ensure that auditors conducting assessment meet the capabilities described in ISO 19001 and ISO 22003 with specific regard to audits against GFSI Approved Standards.

7.6.8 Non conformity definitions	Removed The definition of ISO/IEC Guide 61:1996 for non-conformities is to be used. (also see chapter 3)		
7.6.9 Ranking and scoring systems	Renamed and revised A ranking and scoring system, when used, must ensure that the fundamental issue of whether a site is in compliance with a standard is clearly expressed.	7.8 Evaluation	Where scoring, ranking and grading systems are applied, they must be clearly explained by the Standard Owner. The audit report must clearly express where the site is in compliance, or not in compliance, with the Standard. In the case where a non-conformity is identified by the auditor, clear and concise details of a non-conformance shall be provided in the audit report.
7.6.10 Corrective actions	Revised A system must be in place to ensure that all corrective actions have been satisfactorily closed within agreed timescales, and with full reference to the requirements of ISO/IEC Guide 65.	7.9 Corrective Action of Non Conformities	All non conformities, as defined in Part I Section 3, must have corrective action plans and evidence of implementation submitted for the Certification Body to verify that the applicant meets the requirement of the Standard. Verification may take the form of further on-site assessment or of submitted paperwork including updated procedures, records, and photographs etc, assessed by a technically competent member or group within the Certification Body. All evidence of corrective action must be returned, completed and verified by the Certification Body within a timescale defined in the Standard before certification can be awarded.
7.6.11 Certification decision	Revised All decisions concerning the issuing of a certificate shall be made with full reference to ISO/IEC Guide	7.10 Certification Decision	The Standard Owner must require that each assessment report is given a thorough technical review prior to granting, suspending, withdrawing

	<p>65. In particular, the record of any site undergoing certification shall be complete, and will include details of all work done by all certification bodies.</p>		<p>or renewing certification. The review shall ensure</p> <ul style="list-style-type: none"> - that reviewers are impartial and technically competent to understand the content of reports and that the reports accurately assessed to demonstrate satisfactory evidence of compliance with the scheme - that all requirements of the standard have been fully covered, using any supporting notes made during the assessment by a suitably qualified auditor. - that the scope of the report covers the scope applied for by the client, and that the report provides satisfactory evidence that all areas of the scope have been fully investigated. - that all areas of non-conformity have been identified, and effective corrective action has been taken to resolve these non-conformities. <p>The client must be made aware that they can appeal against the certification decision.</p>
<p>7.6.12 Audit reports</p>	<p>Removed Process and format shall be clearly defined by the Standard Owner, in compliance with chapter 7.3.</p>		
<p>7.6.13 Distribution of audit reports</p>	<p>Revised All audit reports shall be made available to authorised parties. Authorisation for access shall remain with the site, but once a party has been authorised, the full record of all certification activity and all reports shall be made available.</p>	<p>7.11 Distribution of Audit Reports</p>	<p>Audit reports shall be made available to authorised parties, at the discretion of the contracted client. Ownership of the audit report, determination of details made available and authorisation for access shall remain with the contracted client.</p>

	<p>7.5.5 Extension of scope</p>	<p>ADDITIONAL REQUIREMENT In order to extend scope, an auditor must undergo a programme of theoretical training in the new category, conduct supervised audits and must be assessed and signed off as competent by the Certification Body to audit in the new category.</p>
	<p>7.5.6 Audit experience</p>	<p>ADDITIONAL REQUIREMENT Initial Audit Experience Auditors must have successfully completed a period of supervised training in practical assessment through 10 audits or 15 audit days, at a number of different organisations against the relevant GFSI approved standard.</p> <p>Maintain Audit Experience The CB must have in place an annual programme to include at least 5 audits or 10 audit days of on site auditing at a number of different organisation, against the relevant GFSI approved standard and to maintain category and scheme knowledge, with sign off for auditor re-approval.</p>
	<p>7.5.7 Continued Training</p>	<p>ADDITIONAL REQUIREMENT The auditor must be kept up to date with category best practice, have access to and be able to apply relevant laws and regulations and shall maintain written records of all relevant training undertaken.</p>
	<p>7.5.8 Attributes and Competenci es</p>	<p>ADDITIONAL REQUIREMENT The Certification Body must have a system in place to ensure auditors conduct themselves in a professional manner. The following provide examples of required behaviour.</p> <ul style="list-style-type: none"> • Ethical, i.e. fair, truthful, sincere, honest and

discreet.

- Open minded, i.e. willing to consider alternative ideas or points of view.
- Diplomatic, i.e. tactful in dealing with people.
- Observant, i.e. actually aware of physical surroundings and activities.

- Perceptive, i.e. instinctive, aware of and able to understand situations.
- Versatile, i.e. adjust readily to different situations.
- Tenacious, i.e. persistent, focussed on achieving objectives.
- Decisive, i.e. timely conclusions based on logical reasoning.
- Self reliant, i.e. acts independently whilst interacting effectively with others.
- Integrity – aware of need for confidentiality and observing professional code of conduct.

7.6 Conflict of Interest

ADDITIONAL REQUIREMENT

The Certification Body and the Auditors they employ must avoid any conflict of interest, with particular regard to auditing, training and consultancy, and must sign Confidentiality Agreements to demonstrate commitment in this regard.

N.B. Definition of Conflict of Interest – Part I, Section 3