



The Global Food Safety Initiative

Addendum to the GFSI Guidance Document Fifth Edition

Date of Issue: 15th December 2009

Introduction

The GFSI Board has approved this addendum to the GFSI Guidance Document Fifth Edition (September 2007) (“the Guidance Document”). The date of issue of the addendum is 15th December 2009 and the requirements of this document take immediate effect from that date.

Scope of Application

This addendum applies to any scheme holding conditional GFSI recognition status, those schemes who are currently in the benchmarking process with the aim of achieving formal application for recognition to the GFSI requirements and any other scheme that puts forward an application for recognition between the date of issue of this addendum and the issue of the Sixth Edition of the GFSI Guidance Document.

This addendum shall have no effect on schemes which have full GFSI recognition as of 14th December 2009, against the requirements laid out in Guidance Document Version 5, issued September 2007 ;

- BRC Global Standard Version 5
- Dutch HACCP (Option B) Revision June 2006
- International Food Standard Version 5
- SQF 2000 Level 2 - 6th Edition
- GlobalGAP (Fruit and Vegetable Scope Options 1 and 2 only) V 3.0
- Global Red Meat Standard Version 3

This addendum does not apply to any scheme that are currently in the benchmarking process with the aim of achieving formal application for recognition that has demonstrable evidence that a national Accreditation Body has accredited a Certification Body(s) to ISO/IEC Guide 65:1996 for the scope of their certification standard.

The following requirements have been taken from the Guidance Document and amended. These requirements shall replace the specified requirements laid down in the Guidance Document Version 5, Issued September 2007. All other requirements of the Guidance Document Version 5 Issued September 2007 still apply.

3. Global Food Safety Initiative Definitions

Audit

Systematic and functionally independent examination to determine whether activities and related results comply with a conforming scheme’s standard, whereby **all** the elements of this standard should be covered by reviewing the suppliers’ manual and related procedures, together with an evaluation of production facilities.

Certification scheme

Scheme consisting of a certification standard and certification system as related to specified processes or a food safety management system to which the same particular scheme applies. The certification scheme should contain at least the following items:

- a standard
- a clearly defined scope
- a certification system, including:
 - requirements for the qualifications of auditors
 - a statement of approximate duration and frequency of visits
 - the minimum content of the audit report.

Certification standard

A normative document and other defined normative documents, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

Recognised body

A legal entity that represents the interests of a food industry sector or a federation of national standards bodies

Surveillance

Follow-up audit(s) to assess compliance with the specific requirements of a scheme's standard and to verify the validity of an issued certificate.

4. Overview of the GFSI Guidance Document

4.2 Basis for the Key Elements

The Key Elements cover the whole range of the food safety criteria to be complied with, in relation to the certification standard, and any other scheme specific normative documents:

- Food Safety Management Systems
- Good Practices
- Hazard Analysis and Critical Control Point (hereafter, HACCP) principles, as defined by the Codex Alimentarius Commission or the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

5. Procedure for the application for benchmarking of food safety management schemes

5.3 References

- ISO 19011:2002 Guidelines for quality and/or environmental systems auditing. ISO/IEC 17007:2009 Conformity assessment -- Guidance for drafting normative documents suitable for use for conformity assessment.

- ISO/IEC Guide 65:1996 General requirements for bodies operating product certification systems.
- ISO/IEC Guide 2:2004 Standardisation and related activities – General vocabulary.
- ISO 9000:2005 Quality Management Standards – fundamentals & vocabulary.
- ISO/IEC 17021:2006 Conformity assessment- Requirements for bodies providing audit and certification of management systems.
- ISO/TS 22003:2007 Food safety management systems- Requirements for bodies providing audit and certification of food safety management systems.
- ISO/IEC 17000:2004 Conformity assessment- Vocabulary and general principles.

5.5.2 Maintenance of the Requirements for delivery of Food Safety Management Systems

5.5.2.1 GFSI has also set the requirements for the delivery of food safety management systems. Each certification body operating a scheme must be accredited by an accreditation body, which is a member of the International Accreditation Forum (IAF) and which is also a party to the Multi Lateral Arrangement (MLA) of ISO/IEC Guide 65 or equivalent (see section 7.2), as far as such MLA exists.

5.6 Conforming Scheme

The owner of a conforming scheme shall ensure that the scheme (standard and certification system) has been developed in compliance with the requirements of ISO/IEC Guide 65 or equivalent (see section 7.2).

5.7.1.2

GFSI shall require that the conforming scheme owner:

(a) has documented arrangements with individual certification bodies operating the conforming scheme that ensure that the certification body operates in compliance with all the requirements of the GFSI Guidance Document and ISO/IEC Guide 65 or equivalent (see section 7.2).

5.7.3 Requirements of a conforming scheme

The scheme shall: a) have been developed with the participation of technically competent representatives of direct stakeholders, or have been subjected to formal review by such parties and subsequently revised as appropriate.

b) have achieved agreement with at least two national Accreditation Bodies for Certification Bodies to operate to ISO Guide 65 or equivalent (see section 7.2) for the scope of their food safety management scheme. The Accreditation Bodies shall be members of IAF .

c) be reviewed and updated, at least every five years, with the involvement of representatives of direct stakeholders (see clause 5.11).

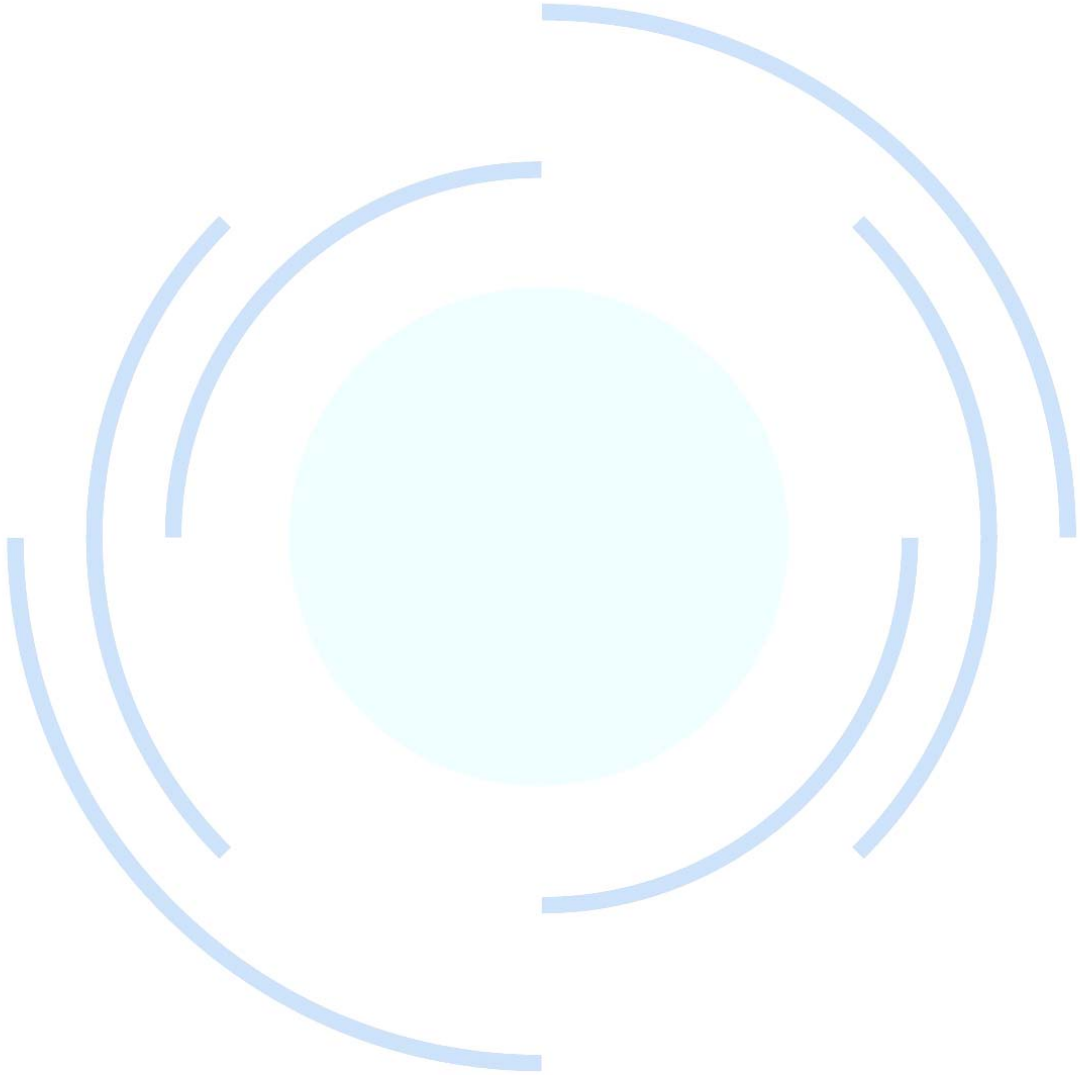
(d) have copyright which is held by an identified legal entity, or have made appropriate application for such copyright.

(e) 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.

(f) have credibility with industry, appropriate regulatory authorities or relevant professional groups. Any new schemes for benchmarking against the GFSI Guidance Document must be supported by the written support of two retailers.

(g) be publicly available with its use for certification purposes to be open, without restriction by membership or other limitation. The levying of a reasonable fee for the purchase of the scheme, a license fee for its implementation, or a training requirement for the application of the scheme, will not be regarded as a restriction or a limitation.

(h) not allow products produced under the conforming scheme to be labeled, marked or described in a manner which implies that they meet a standard or specification for a particular product.



7. Requirements for the delivery of food safety management systems

7.2 Guidance for the Management of Certification Bodies

The core principles upon which certification should be based are as follows:

- impartiality
- competence
- responsibility
- openness
- confidentiality
- responsiveness to complaints

The decision as to the most appropriate generic Standard to be used to accredit Certification Bodies for the scope of a scheme shall rest with Accreditation Bodies (see section 5.7.3 [b]).

The GFSI bases its criteria for acceptance of food safety management schemes on two sets of general accreditation requirements for certification bodies;

1. The generic International Standard ISO/IEC Guide 65 – General requirements for bodies operating product certification systems,

OR

2. The generic International Standard ISO/IEC 17021:2006 (Conformity assessment- Requirements for bodies providing audit and certification of management systems) and supplemented by ISO/TS 22003 (Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems).

In the case of scheme wishing to use ISO /IEC 17021 :2006 and ISO/TC 22003, any requirements specified in section 7 or section 7 Annex 1 of this Guidance Document shall be in place in order to ensure full compatibility with ISO/IEC Guide 65 and shall supersede the requirements of ISO/IEC 17021:2006 and ISO/TC 22003.

7.2.1 Accreditation

Food safety management schemes 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 or ISO/IEC 17021:2006 and ISO/TC 22003.

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.

Under certain circumstances, the Certification Body may have an application for extension of their scope pending with an Accreditation Body. They will however, have a current accreditation to

ISO/IEC Guide 65 or ISO/IEC 17021 and ISO/TC 22003. Written notification of such a circumstance from the food safety management scheme owner must be held by the Certification Body.

The range of certification services offered by a body may be wider than those accredited. In this case the limits of the accreditation shall be made clear. Services that are outside the scope of the accreditation shall be distinguished from those that are accredited.

7.3.2 The Certification Body must define the frequency of audit for each site and must clearly define the rationale for the determination of frequency within the scheme.

Audit frequency will be at a minimum of 12 months. Each audit will be undertaken to assess compliance with the **full** requirements of the conforming scheme's standard and reported on.

The frequency of audits may be influenced by a number of factors such as previous audit history, concerns upon compliance with scheme's standard, 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.

7.5 Auditor Qualifications, Training, Experience and Competencies

Independent of the scope of accreditation, the Certification Body must have systems and procedures in place to ensure that auditors conducting assessment meet the capabilities described in ISO 19011 and ISO 22003 with specific regard to audits against GFSI recognised Schemes and all requirements listed in sections 7.5.1 to 7.5.4.

7.5.1 Qualification/Education

A degree in a food related or bioscience discipline, or as a minimum, has successfully completed a food related or bioscience higher education course or equivalent.

Part 1 Annex 1 Additional requirements for Certification Bodies and scheme owners choosing accreditation according to ISO/IEC 17021 and ISO/TC 22003

1. The scheme owner and Certification Body will recognize the definition of supplier as; *'the party that is responsible for ensuring that products meet and, if applicable, continue to meet, the requirements on which the certification is based.'*

2. The certification body shall take all steps required to evaluate conformance with the standard and fully comply with other associated requirements of the certification scheme.

3. The certification body shall operate an effective and fully implemented quality system. The quality system shall be fully documented and used by all relevant certification body staff. Within the certification body there shall be a designated member of staff responsible for the quality system's development, implementation and maintenance. This designated member of staff will have a reporting role to the organisation's executive and shall also have the responsibility for reporting on the performance of the quality system for the basis of management review and subsequent system improvement.

4. The required quality system shall be fully documented within a quality manual, which in turn will contain all necessary procedures for compliance. As a minimum, the quality manual shall contain:

- I. A quality policy statement.

- II. A description of the legal status of the organization, including ownership, and an organizational structure including named individuals their job titles and description of responsibilities. The organizational structure shall include a chart listing each job title and how these functions interrelate through a management structure.
- III. A list of named individuals employed by the organization which includes their qualifications and full details of their experience.
- IV. A description of the management of the certification process including its committee structure, terms of reference and procedures.
- V. Details of management review policy and procedures.
- VI. Procedures in relation to documentation control.
- VII. Details of operational and functional responsibilities pertaining to quality defining an individual limits of responsibility and accountability.
- VIII. Recruitment procedures, i.e. selection, initial training, ongoing training and performance assessment for all relevant certification body personnel.
- IX. A list of all subcontractors and a detailed procedure for their appointment, assessment and their ongoing management.
- X. Procedures for actions in response to non conformities the effectiveness of agreed corrective and preventative actions taken.
- XI. Procedures in relation to the use of the certificate and in the event of the requirement to withdraw or suspend certification the actions taken by the certification body.
- XII. Policy and procedures relating to appeals, complaints and disputes.
- XIII. Procedures for conducting internal audits and corrective actions arising from internal audits.

5. In the event of significant change which could affect the safety of product, changes to the requirement of the certification scheme standard, change of ownership or management of the supplier or the Certification Body has reason to believe there could be compliance issues in relation to certification, the Certification Body shall re-evaluate the supplier(s) to assess compliance with the certification scheme standard.

6. The Certification Body shall make available the following information at all times:

- I. Authority under which the organization operates.
- II. Statement in relation to its certification system, including information on rules and procedures for granting, maintaining, extending, suspending and withdrawing certification of its clients.
- III. Evaluation procedures and certification process in relation to the certification scheme.
- IV. Details of the means of obtaining financial support and fees charged to clients.
- V. Details of the rights and requirements of applicants and clients such as the use of logo and marks and the way in which a client can use information in relation to certification.
- VI. Details of complaints, appeals and disputes procedures.
- VII. A comprehensive list of all certificated clients against the scope of the certification scheme's standard.

7. The Certification Body shall require all staff involved with the certification process to sign a contract or agreement which clearly commits them to

- I. Complying with the rules of the organization, with particular reference to confidentiality and independence from commercial or personal interests
- II. Declaring any issues in relation to personal conflicts of interest.

The certification body shall clearly document and make known to its employees all requirements in ISO 17021 related to personnel.

8. The Certification Body shall hold and maintain records regarding qualifications, training and experience of all staff involved in the certification process. All records shall be dated. The information shall include as a minimum:

- I. Name and address
- II. Organisation affiliation and position held
- III. Educational qualification and professional status
- IV. Experience and training in the relevant fields of competence in relation to the certification scheme's requirements
- V. Details of performance appraisal

