Global Food Safety Initiative

GFSI Requirements on the Application of ISO/IEC 17011:2004

Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies

Introduction

CIES-- The Food Business Forum is the only independent global food business network. It brings together the CEOs and senior management of around 400 retailer and manufacturer members of all sizes, across 150 countries.

CIES has been growing with the food business for 55 years. It provides a real global platform for thought leadership, debate and networking between retailers and their partners. Its strength lies in the privileged access it offers to the key players in the sector and the sharing of best practice at the highest level. It has a mandate from its members to develop common positions on key strategic and practical issues affecting the food business.

The Global Food Safety Initiative (GFSI), co-ordinated 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.

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 GFSI Technical Committee, an international multi-stakeholder group of over 50 food safety experts. The GFSI Technical Committee works on specific selected projects throughout the year, approved by the GFSI Foundation Board in order to fulfil the GFSI Mission; these have included projects such as auditor competence, food defence and technical issues relating to emerging and developing markets.

In 2008 the GFSI Foundation Board formed the GFSI Accreditation Task Force whose purpose is to:

- agree on common areas of concern in relation to the accreditation process, by undertaking a review of current documents from GFSI benchmarked schemes regarding the relationship between Certification Bodies and Accreditation Bodies, in order to identify and define common requirements and individual requirements
- gain and collate information from GFSI benchmarked scheme owners on any operational issues regarding the accreditation process and seek their agreement to act on their behalf regarding the development of common requirements
- review the agreed common requirements identified against ISO17011 and put forward areas where ISO 17011 can be more specific in relation to the requirements of GFSI recognised schemes
- develop and agree a Requirements document defining common requirements for Accreditation Bodies in relation to ISO 17011 and GFSI recognised schemes
- use the agreed Requirements document as the basis for discussion with International Accreditation Forum and European Accreditation, with a view to gaining recognition of the document by these organisations
- agree implementation criteria for the proposed Requirements documents allowing GFSI to act on the behalf of the Accreditation Task Force and GFSI recognised standards owners
- undertake the review of the progress of the development and implementation of the Requirements documents and advise the GFSI Foundation Board accordingly.

The Purpose of the GFSI Requirements on the Application of ISO /IEC 17011

ISO/IEC 17011:2004 is an International Standard which sets out criteria for conformity assessment for Accreditation Bodies accrediting conformity assessment bodies. There are no specific requirements in relation to those Accreditation Bodies carrying out assessment of conformity assessment bodies working with food safety schemes.

Since 2000 the GFSI has worked closely with a number of major stakeholders in the food industry in an attempt to harmonise processes related to food safety schemes and has benchmarked and recognised four post farm gate schemes.

Over a period of time, each of these schemes has developed their own set of criteria in relation to the accreditation process which has lead to a diversity of requirements; this in turn has lead to complexity of process,, increased cost and a lack of clarity.

The GFSI Accreditation Task Force was formed in February 2008 with an objective to facilitate dialogue between GFSI recognised scheme owners and other interested parties in order to harmonise their approach and minimise the effects that the diversification of requirements has caused.

This document is the culmination of work undertaken by GFSI and the four GFSI recognised scheme owners to specify harmonised requirements in relation to the accreditation of conformity assessment bodies carrying out product certification to the GFSI recognised schemes.

The document has been entitled 'Requirements' to reflect that this document is not regarded as guidance notes and will be the subject of further work with the GFSI and the GFSI recognised scheme owners to ensure compliance with the specified requirements by those Accreditation Bodies working with GFSI recognised schemes.
.
The term 'shall' is used in the document to indicate those provisions which are regarded as being mandatory. There are requirements within the document which are specific with respect to parameters of assessment; these shall be regarded as minimum requirements and do not preclude Accreditation Bodies carrying out increased activity in the event that they would wish to, or deem it appropriate to do so.

The GFSI wishes to continue work closely IAF and its members in a spirit of co-operation to ensure the implementation of these requirements, which will provide enhanced confidence regarding the accreditation of conformity assessment bodies working within the food industry.

Content of ISO/IEC 17011

1 Scope

2 Normative references

3 Terms and definitions

4 Accreditation body
4.1 Legal responsibility
4.2 Structure
GFSI Requirements to clause 4.2.4
GFSI Requirements to clause 4.2.6
4.3 Impartiality
4.4 Confidentiality
GFSI Requirements to clause 4.4
4.5 Liability and financing
4.6 Accreditation activity
GFSI Requirements to clause 4.6.1
GFSI Requirements to clause 4.6.2

5 Management
5.1 General
5.2 Management system
GFSI Requirements to clause 5.2.1
5.3 Document control
5.4 Records
GFSI Requirements to clause 5.4.2
5.5 Nonconformities and corrective actions
5.6 Preventive actions
5.7 Internal audits
GFSI Requirements to clause 5.7.2
5.8 Management reviews

5.9 Complaints
GFSI Requirements to clause 5.9

6 Human resources
6.1 Personnel associated with the accreditation body
6.2 Personnel involved in the accreditation process
GFSI Requirements to clause 6.2.1
GFSI Requirements to clause 6.2.3
6.3 Monitoring
6.4 Personnel records

7 Accreditation process
7.1 Accreditation criteria and information
7.2 Application for accreditation
GFSI Requirements to clause 7.2.1
GFSI Requirements to clause 7.2.3
7.3 Resource review
7.4 Subcontracting the assessment
GFSI Requirements to clause 7.4.1
7.5 Preparation for assessment
GFSI Requirements to clause 7.5.6
GFSI Requirements to clause 7.5.8
GFSI Requirements to clause 7.5.10
7.6 Document and record review
GFSI Requirements to clause 7.6.1
7.7 On-site assessment
GFSI Requirements to clause 7.7.2
GFSI Requirements to clause 7.7.3

7.8 Analysis of findings and assessment report
7.9 Decision-making and granting accreditation
GFSI Requirements to clause 7.9.3
GFSI Requirements to clause 7.9.5
7.10 Appeals
7.11 Reassessment and surveillance
GFSI Requirements to clause 7.11.3
GFSI Requirements to clause 7.11.5
GFSI Requirements to clause 7.11.6
GFSI Requirements to clause 7.11.7
7.12 Extending accreditation
GFSI Requirements to clause 7.12
7.13 Suspending, withdrawing or reducing accreditation
GFSI Requirements to clause 7.13.2
GFSI Requirements to clause 7.13.3
7.14 Records on CABs
7.15 Proficiency testing and other comparisons for laboratories

8 Responsibilities of the accreditation body and the CAB
8.1 Obligations of the CAB
GFSI Requirements to clause 8.1.2
8.2 Obligations of the accreditation body
GFSI Requirements to clause 8.2.3
GFSI Requirements to clause 8.2.4
8.3 Reference to accreditation and use of symbols
GFSI Requirements to clause 8.3.2
GFSI Requirements to clause 8.3.3

Additional Requirements to ISO 17011

Requirements on the Application of ISO/IEC 17011:2004

Conformity assessment- General requirements for the accreditation bodies accrediting conformity assessment bodies

1 Scope
No additional requirements

2 Normative References
No additional requirements

3 Terms and definitions
No additional requirements

4 Accreditation body
No additional requirements

4.1 Legal responsibility
No additional requirements

4.2 Structure
GFSI Requirements to clause 4.2.4
The Accreditation Body shall appoint a responsible person within their organisation with authority for GFSI food schemes.

GFSI Requirements to clause 4.2.6
Where there are issues or queries arising during the accreditation process, the Accreditation Body shall consult directly with the GFSI scheme owner representatives.

4.3 Impartiality
No additional requirements

4.4 Confidentiality -

GFSI Requirements to clause 4.4

The Accreditation Body shall share information regarding scheme specific issues with the appropriate representative of each GFSI recognised scheme owner. This information shall be shared as soon as practicable and the accreditation body shall be responsible for the follow-up of the corrective actions in the case of complaints and major non-conformities.

This list of information to be shared, which is not exhaustive but shall include:

- *accreditation status,(suspension, withdrawal, scope reduction or expiry of accreditation),*
- *complaints which could jeopardise the accreditation status,*
- *major nonconformities (a major nonconformity is defined as a nonconformity which has the potential to impact on the validity of a certificate or of certificates issue,.*
- *annual activity summary which shall be made available to the GFSI recognised scheme owners indicating as a minimum:*
  - *General assessment details*
  - *Head office assessment: date, Location, critical location assessments, numbers of site and auditor files reviewed, Accreditation Body's assessors names, duration, general conclusions*
  - *Witness assessment: location, date, field, Accreditation Body assessor, duration, general conclusions*
  - *CAB name and conclusion of reports - Accreditation Status*

The annual activity summary shall be in a standardised format as agreed by GFSI (see appendix).

There shall be an agreement regarding confidentiality between the AB and the GFSI recognised standards owners. This agreement shall specify that the information shared shall be made known to all GFSI recognised scheme owners, but shall remain confidential from any other party. There shall also be an agreement between the individual CAB's and the GFSI recognised scheme owners.

4.5 Liability and financing

No additional requirements

4.6 Accreditation activity

GFSI Requirements to clause 4.6.1

Normative documents shall include all documentation relevant to GFSI recognised scheme, and shall be issued by a GFSI recognised scheme owner.

GFSI Requirements to clause 4.6.2

These GFSI requirements shall be included as part of this process.

5 Management
No additional requirements

5.1 General
No additional requirements

5.2 Management system
GFSI Requirements to clause 5.2.1
With respect to effective communication, communication channels with interested parties shall be in place and include GFSI and GFSI recognised scheme owners.

5.3 Document control
No additional requirements

5.4 Records
GFSI Requirements to clause 5.4.2
Records shall be maintained and accessible for a period of a minimum of 5 years.

5.5 Nonconformities and corrective actions
No additional requirements

5.6 Preventative actions
No additional requirements

5.7 Internal audits
GFSI Requirements to clause 5.7.2
The internal audit shall include accreditation activities in relation to GFSI recognised schemes.

5.8 Management reviews
No additional requirements

5.9 Complaints
GFSI Requirements to clause 5.9
All complaints associated with any GFSI Scheme shall be investigated and dealt with, as far as possible within 30 days of receipt. If any complaint puts a GFSI recognised scheme certificates/approvals, at risk, then the GFSI scheme owner shall be informed immediately and appropriate action taken by the Accreditation Body.

6 Human Resources
No additional requirements

6.1 Personnel associated with the accreditation body
No additional requirements

6.2 Personnel involved in the accreditation process
GFSI Requirements to clause 6.2.1
All AB personnel engaged in GFSI recognised scheme accreditation activity shall have sufficient knowledge of each relevant GFSI recognised scheme, related normative documents and the food industry.
The AB shall ensure the assessment team undertaking witness activities includes personnel who have completed training in the relevant GFSI scheme, successfully completed a HACCP training course and have an individual with a minimum of two years experience in the food industry sector.
The assessment team carrying out office assessments shall include personnel who have a specific knowledge of the relevant GFSI schemes being assessed and the related normative documents.
Training in the GFSI recognised scheme shall be recognised by respective scheme owners.

GFSI Requirements to clause 6.2.3
The Accreditation Body shall document information regarding assessors and experts in accordance with the GFSI requirements in section 6.2.1.

6.3 Monitoring
No additional requirements

6.4 Personnel records
No additional requirements

7 Accreditation process
No additional requirements

7.1 Accreditation criteria and information
No additional requirements

7.2 Application for accreditation
GFSI Requirements to clause 7.2.1
The Certification Body shall demonstrate that they have made appropriate contact with the scheme owner during the application procedure.

GFSI Requirements to clause 7.2.3
The AB shall inform a GFSI scheme owner when an application is made to accredit against a GFSI recognised scheme.

7.3 Resource review
No additional requirements

7.4 Subcontracting the assessment
GFSI Requirements to clause 7.4.1
If the AB subcontracts an assessment, the assessment shall be carried out in accordance with this document and the individual GFSI scheme owner's requirements. The sub contracted AB shall be a signatory to the IAF MLA for Product Certification and the assessor shall fulfil the competence requirements outlined in this document. Where additional formal agreements exist, e.g. IAF GD 3 Cross Frontier Policy. There shall be compliance with these agreements. The AB using subcontractors shall review the compliance with these requirements.

7.5 Preparing for assessment
GFSI Requirements to clause 7.5.8
During the surveillance and reassessments, the following documentation shall be sampled and assessed as a minimum:
1. Sample of at least 10% or 2 auditor files, whichever is greater, for each GFSI scheme
2. Sample of at least 2 site files, for each GFSI scheme or 2% delivered audits, whichever is greater, for each GFSI scheme
3. Sampling of site files shall be risk-based and should be done across country (region), product category and assessor
4. The site file assessments shall include a review of:

- *Contracts between the CAB and the client*
- *Confirmation of audit scope and duration*
- *Auditor's original notes from audit and evidence of compliance*
- *Documentary evidence supplied by the client for non-conformities identified*
- *Final audit report*
- *Certification Decision and Certificate Conformity*

Sampling levels shall be increased where evidence of issues are identified during the assessment in order to satisfy whether the certification body is meeting accreditation requirements.

Where objective evidence or complaints are identified between planned surveillance and reassessments, accreditation bodies shall carry out additional assessments.

GFSI Requirements to clause 7.5.10
The AB shall ensure that the GFSI standard owner documentation is included. The AB shall request, through direct communication with the GFSI standard owner, any feedback or relevant information concerning the CAB in advance of the assessment.
*The AB shall take into account during the assessment, any feedback or relevant information concerning the CAB sent by a GFSI recognised scheme owner. The AB must verify during the assessment, that these complaints have been dealt with effectively and any corrective actions put in place..**
**'Appropriate criteria documents' referred to in ISO/IEC 17011 shall include the certification body criteria established by the GFSI recognised scheme owner.*

7.6 Document and record review
GFSI Requirements to clause 7.6.1
The GFSI requirements specified in relation to clauses 7.7.2 shall apply in addition to that required under clauses 7.2.1 and 7.2.2.

7.7 On - site assessment
GFSI Requirements for clause 7.7.2
During the initial assessment against the scope of any GFSI recognised scheme (ie. An extension to scope, cf 7.12), the following documentation shall be sampled and assessed:
1. Sample of at least 1 auditor files for the GFSI scheme
2. Sample of at least 1 site files for the GFSI scheme
3. Sampling of site files should be done across country (region), product category and assessor
4. The site file assessment shall include a review of:
- *Contracts between CAB and client*
- *Confirmation of audit scope and duration*
- *Auditor's original notes from audit and evidence of compliance*
- *Documentary evidence supplied by the client for non-conformities identified*
- *Final audit report*
- *Certification Decision and Certificate Conformity*

5. Evaluation and verification of the effectiveness of the CAB's processes for assessment of auditor competence

GFSI Requirements to clause 7.7.3
At least one assessment of the CAB shall be witnessed for initial accreditation for each GFSI recognised scheme. In the event that the CAB wishes to increase their scope with respect to product category this level of sampling shall be increased.

With CABs with more than 20 auditors then witness assessments shall be carried out at a rate of at least 1 witness assessment per 20 auditors per year, auditing against any of the GFSI recognised schemes. Where international CAB have geographical spread then the % of witness audits will be proportional to the geographic spread e.g. 30% overseas then 1 in 3 witnessed audits will be performed overseas. The witness assessment programme shall be designed to ensure different auditors and different product categories are assessed at subsequent witnessed assessments.

7.8 Analysis of findings and assessment report
No additional requirements

7.9 Decision-making and granting accreditation
GFSI Requirements to clause 7.9.3
If the AB subcontracts an assessment, the assessment shall be carried out in accordance with this document and the individual GFSI scheme owner's requirements. The sub contracted AB shall be a signatory to the IAF MLA for Product Certification and the assessor shall fulfil the competence requirements outlined in this document. Where additional formal agreements exist, e.g. IAF GD 3 Cross Frontier Policy. There shall be compliance with these agreements. The AB using subcontractors shall review the compliance with these requirements.

GFSI Requirements to clause 7.9.5
The accreditation certificate or schedule shall include the full name and version of the GFSI recognised scheme, and the GFsI recognised scheme's designated product categories for which they are approved .

7.10 Appeals
No additional requirements

7.11 Reassessment and surveillance
GFSI Requirements to clause 7.11.3

- *Head office shall have an assessment on an annual basis.*
- *A witness assessment of a CAB shall be conducted by the AB at least 1 per year for each CAB. All GFSI recognised schemes will be witnessed in a 4 year cycle.*
- *With CABs with more than 20 auditors then witness assessments shall be carried out at a rate of at least 1 witness assessment per 20 auditors per year, auditing against any of the GFSI recognised schemes. Where international CAB have geographical spread then the % of witness audits will be proportional to the geographic spread e.g. 30% overseas then 1 in 3 witnessed audits will be performed overseas. The witness assessment programme shall be designed to ensure different auditors and different product categories are assessed at subsequent witnessed assessments.*
- *Reassessment shall be undertaken at least every four years.*

GFSI Requirements to clause 7.11.5
The AB shall inform the GFSI scheme owner about any major nonconformities.(Ref clause 4.4; a major nonconformity is defined as a nonconformity which has the potential to impact on the validity of a certificate or of certificates issue.)

GFSI Requirements to clause 7.11.6
The AB shall inform the GFSI scheme owner if accreditation is suspended, withdrawn or expired or scope is reduced.

GFSI Requirements to clause 7.11.7
When informed of identification of issues in a particular market, which could bring the credibility of the certification process into disrepute, the AB shall take any appropriate action including conduct of an extraordinary assessment if necessary.

7.12 Extending accreditation
GFSI Requirement to clause 7.12
A full initial assessment shall be undertaken for every GFSI recognised scheme, upon an application to extend a scope of ISO Guide 65 to include a new GFSI recognised scheme.

In the event that the CAB wishes to increase their scope of activity with respect to product category as defined by GFSI recognised scheme owners, the accreditation body shall as a minimum undertake an adequate check of documentary evidence to ensure the requirements of the GFSI recognised standards are in place.

7.13 Suspending, withdrawing or reducing accreditation

GFSI Requirements to clause 7.13.2
When GFSI recognised scheme owners requirements are not met, the GFSI scheme owner will inform the AB. The AB shall undertake an investigation of the issues raised by the GFSI recognised scheme owner and shall take appropriate action e.g. to suspend or withdraw accreditation.

GFSI Requirements to clause 7.13.3
When GFSI recognised scheme owner's requirements are not met, the GFSI scheme owner will inform the AB, The AB shall undertake an investigation of the issues raised by the GFSI recognised scheme owner, who shall take appropriate action i.e the decision to reduce the scope of accreditation.

7.14 Records of CABs
No additional requirements

7.15 Proficiency testing and other comparisons for laboratories
No additional requirements

8 Responsibilities of the accreditation body and the CAB
No additional requirements

8.1 Obligations of the CAB

GFSI Requirements to clause 8.1.2 (f)
In the event that GFSI recognised scheme owners suspends or withdraws recognition for a CAB, or reduces scope, in addition to the notification by the CAB, the scheme owner shall also inform the AB.

8.2 Obligations of the accreditation body
GFSI Requirements to clause 8.2.3
The AB shall provide this information, where applicable, to GFSI recognised scheme owners.
The AB shall inform the CABs that they are signatories to the GFSI requirements to ISO/IEC 17011.

GFSI Requirements to clause 8.2.4
In the event of changes or revisions to a GFSI recognised standard, the AB shall collaborate and communicate with the scheme owner to identify the appropriate review process of the CAB, and to ensure that the CAB is aware of and meets the additional/changed requirements in relation to accreditation requirements.

8.3 Reference to accreditation and use of symbols

GFSI Requirements to clause 8.3.2
The AB shall verify that 8.3.2, points (a-f), are applied in connection with the usage of the GFSI recognised schemes.

GFSI Requirements to clause 8.3.3
The AB shall verify that 8.3.2 points (a-f), are applied in connection with the usage of the GFSI recognised schemes and appropriate action taken in the event of incorrect or misleading claims in relation to the use of such information and accreditation status .

Additional Requirements to ISO 17011

1. Activity Summary

An annual activity summary shall be made available to GFSI on all recognised schemes indicating as a minimum:

- *General assessment details*
- *Head office assessment: date, Location, critical location assessments, numbers of site and auditor files reviewed, Accreditation Body's assessors names, duration, general conclusions*
- *Witness assessment: location, date, field, Accreditation Body's assessor, duration, general conclusions*
- *CAB name and conclusion of reports - Accreditation Status*

2. Signatories to MLA

AB's wishing to work with the GFSI requirements to ISO 17011, shall be required to be signatories to the IAF and IAF regional accreditation groups whose product MLA is recognised by the IAF.

GFSI Accreditation Activity Summary

Accreditation Body: Date of Issue:

Certification Body:	Accreditation Status:

GFSI Recognised Standards:

Head Office Assessment
Date of Assessment:
Head Office Location:
Number of site files assessed:
Number of auditor files assessed:
Assessors name:
Duration of assessment:

Other Critical Locations Assessed:

Date of Assessment: Location: Number of site files assessed: Number of auditor files assessed: Assessors name: Duration of assessment:	Date of Assessment: Location: Number of site files assessed: Number of auditor files assessed: Assessors name: Duration of assessment:	Date of Assessment: Location: Number of site files assessed: Number of auditor files assessed: Assessors name: Duration of assessment:

Witness Assessment:

Date of Assessment: Location: Field of Assessment: Assessors name: Duration of assessment: General conclusions:	Date of Assessment: Location: Field of Assessment: Assessors name: Duration of assessment: General conclusions:	Date of Assessment: Location: Field of Assessment: Assessors name: Duration of assessment: General conclusions:
Date of Assessment: Location: Field of Assessment: Assessors name: Duration of assessment: General conclusions:	Date of Assessment: Location: Field of Assessment: Assessors name: Duration of assessment: General conclusions:	Date of Assessment: Location: Field of Assessment: Assessors name: Duration of assessment: General conclusions: