



The Consumer Goods
FORUM

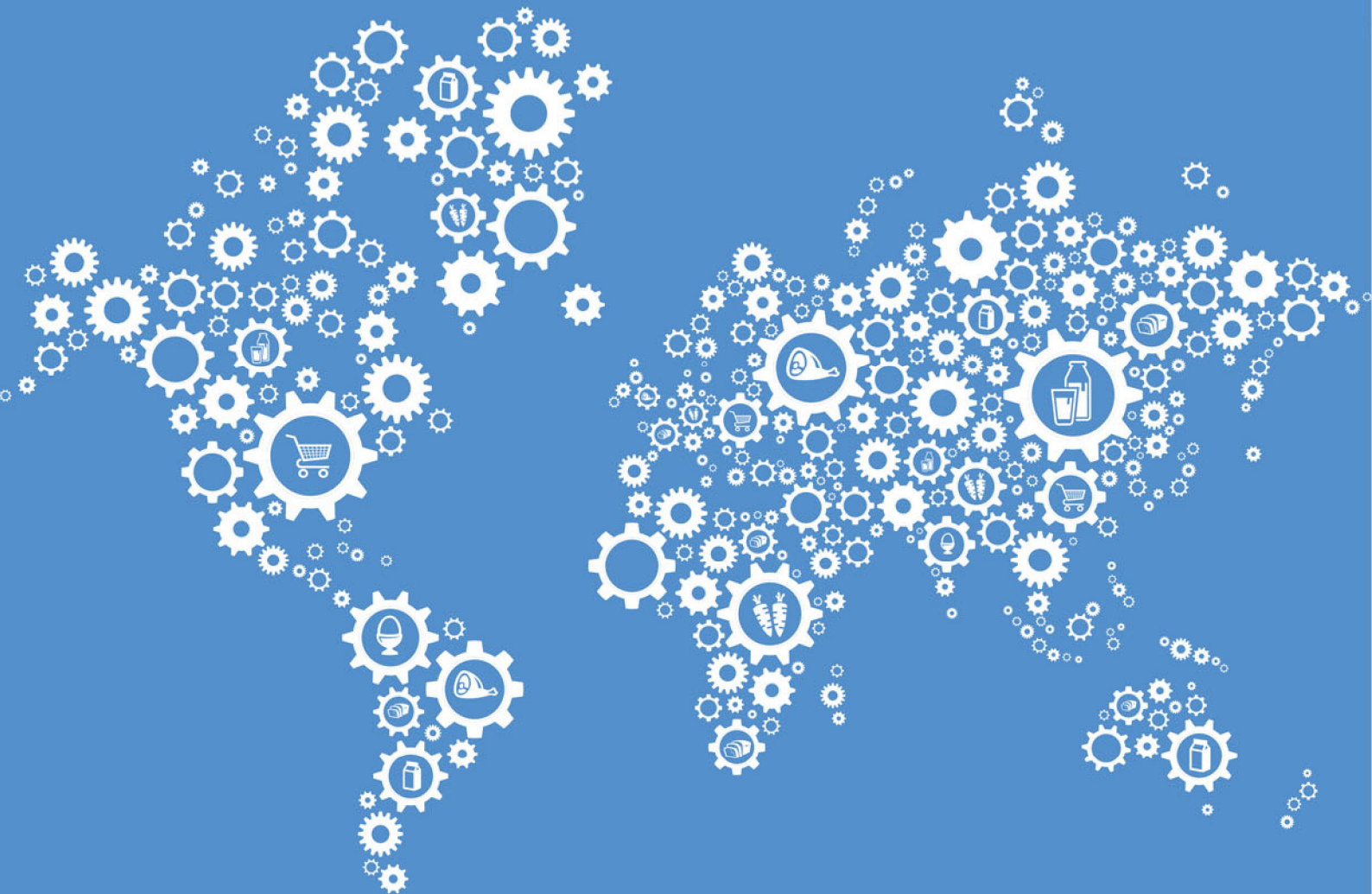


GFSI
Global Food
Safety Initiative

GFSI Global Markets Programme

Manufacturing Protocol

2nd Edition





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1. INTRODUCTION

1.1. The Role of GFSI in the Global Markets Programme

Public-private partnership

GFSI

*Design, develop and manage all documentation
Review and improve the process*

Suppliers

can be mandated by buying companies to progress through the programme.

Buying companies

can mandate their suppliers and support them as they progress through the programme.

Service providers

can partner with buying companies or suppliers to carry out assessments and training against the programme checklists.

International organisations

can use the programme as a basis for capacity building projects, using local experts to ensure relevance.

These entities may work individually or collaboratively, depending on their strategy.

- A Buying Company may work with an Assessment Provider to evaluate their Suppliers.
- An International Organisation may be mandated to work in a country, engaging with local Buying Companies to build capacity in collaboration with local Assessment Providers.

1.2. GFSI Global Markets Programme: Document Plan

Global Markets Programme Protocol

Programme structure applicable for both Primary and Manufacturing.

Training and competency framework

Guidance on training to companies, training providers and learners. Includes a framework of competencies mapped against the checklists.

Checklist: Manufacturing

Basic and Intermediate levels for manufacturing

Checklist: Primary production

Basic and Intermediate levels for primary production

User guidance

Supplementary information:

- What does it mean?
- What do I need to do?
- What will the Assessor check for?

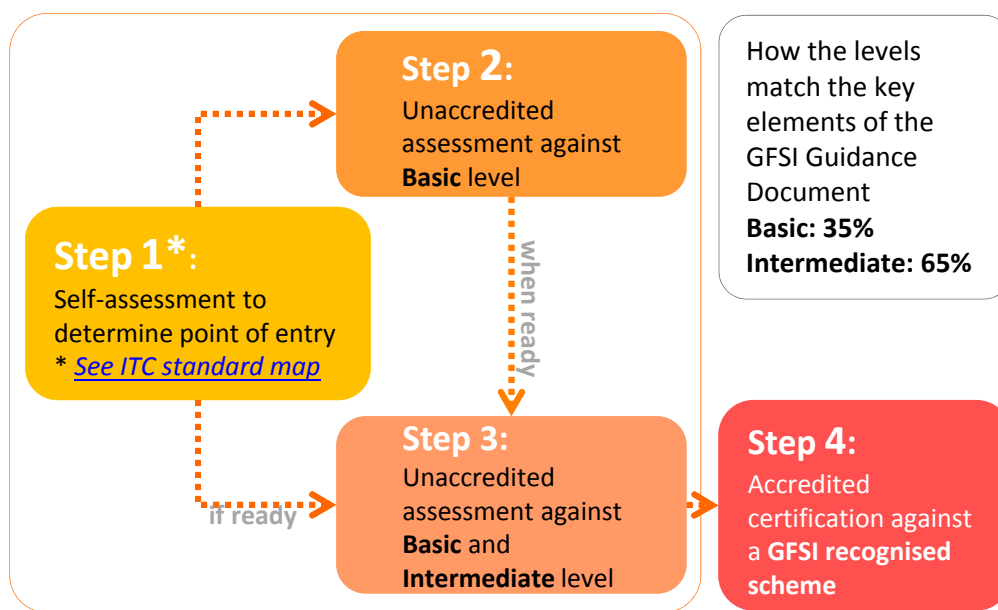
This Protocol has been developed to guide companies through the steps of the Global Markets Programme.

- It provides guidance for assessment against the Basic and Intermediate Level food safety requirements.
- It provides a description of how to register for the Programme, which documents are needed at which stage of the process and how to work with Service Providers.
- This Protocol and the associated documents are subject to the terms of the Disclaimer and the Logo Usage Guideline included in the appendix to this document.



1.3. The Pathway to Certification

A voluntary step-by-step tool for continuous improvement



***International Trade Centre (ITC)** is the joint agency of the World Trade Organisation and the United Nations. It is fully dedicated to supporting the internationalisation of SMEs.

ITC Standards Map is an online platform. It provides comprehensive, verified and transparent information on voluntary sustainability standards and other similar initiatives covering issues such as food quality and safety.

Users are encouraged to enter the [ITC Standards Map GFSI Global Markets Programme Portal](#). They will be able to register their activity and use the specially designed self-assessment tool during Step One.

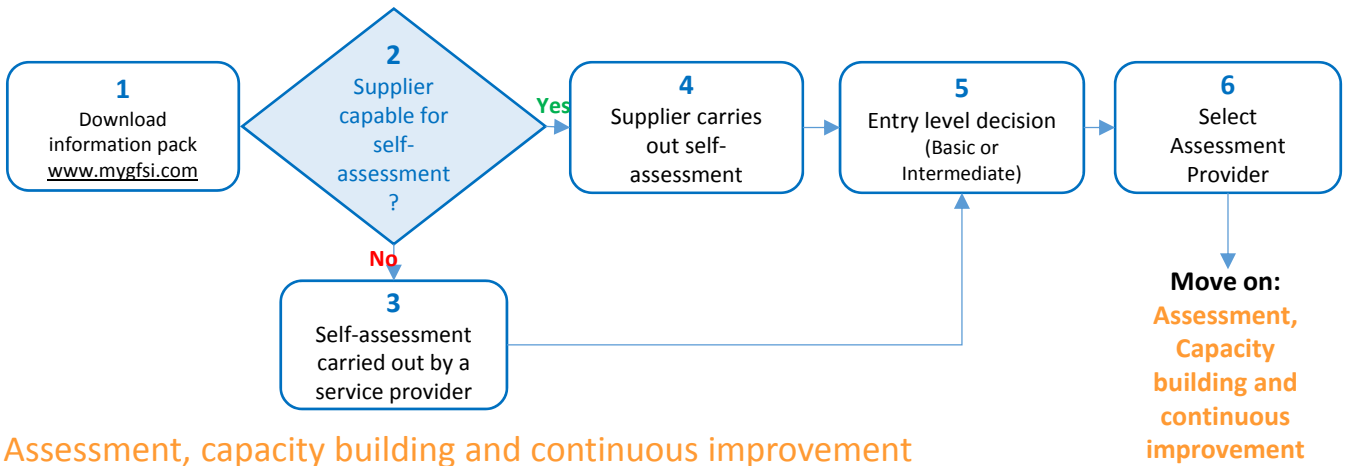
- **Step 1 - Self-Assessment:** Depending on the outcome of the self-assessment, the business should pass to Step 2 (Basic Level), Step 3 (Intermediate Level) or Step 4 (Certification against a GFSI recognised scheme).
- **Step 2 - Assessment Basic Level:** Matches 35% of the GFSI Guidance Document.
- **Step 3 - Assessment Intermediate Level:** Matches 65% of the GFSI Guidance Document.
- **Step 4 - Certification against a GFSI Recognised Scheme:** The official accredited certification process.



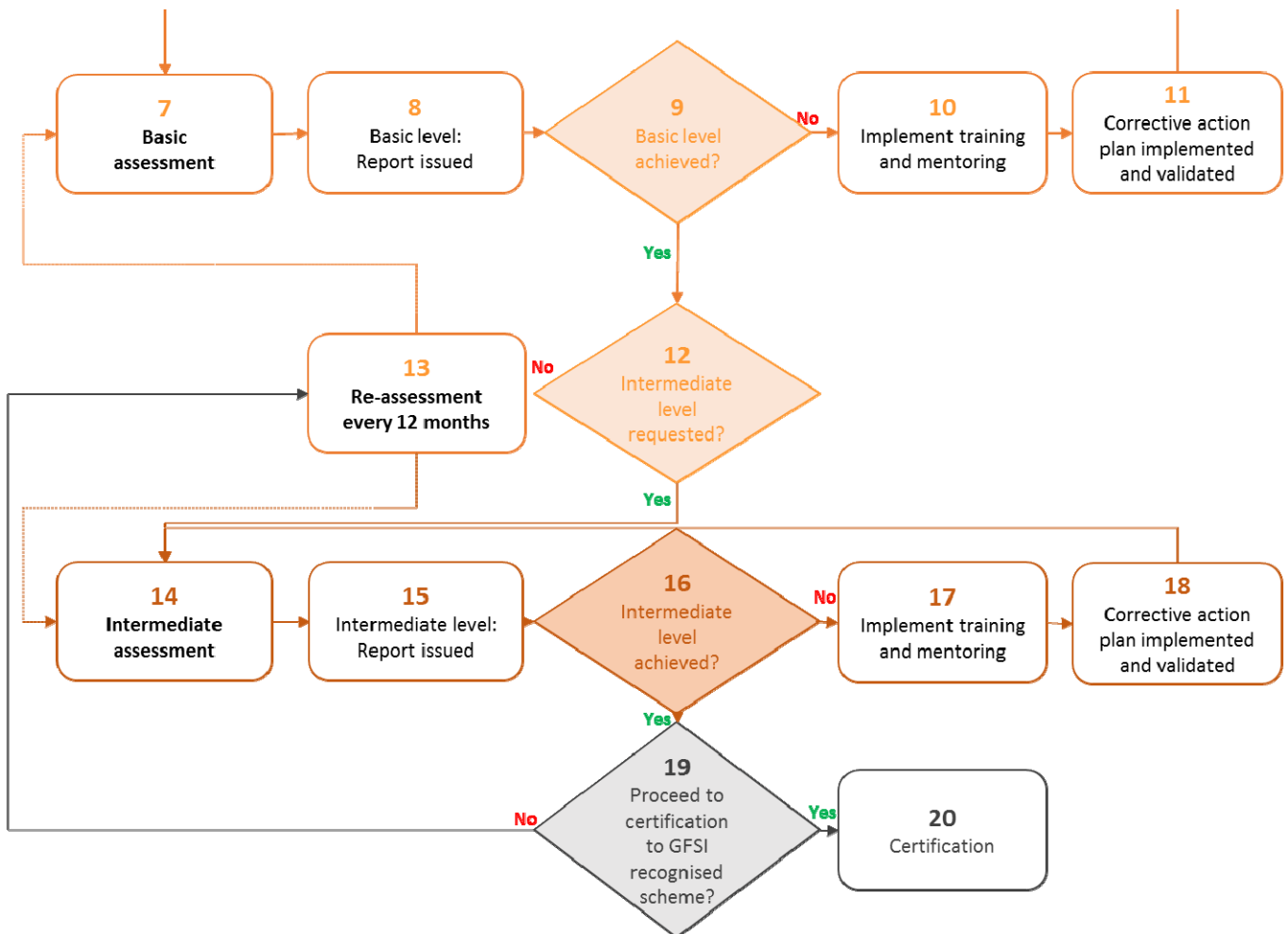
2. PROCESS

2.1. The GFSI Global Markets Programme: Protocol Flowchart

Planning



Assessment, capacity building and continuous improvement



See 'User guidance' (next in this Protocol) for detailed notes on each of these boxes



2.2. User Guidance (1/5)

Box	DESCRIPTION	USER GUIDANCE
PLANNING		
1	Download toolkit (www.mygfsi.com)	<p>All the necessary information on the GFSI Global Markets Programme is available and can be downloaded free of charge from www.mygfsi.com following a short registration process.</p> <p style="text-align: center;"><i>Click on ‘Global Markets Programme’, then click on ‘Toolkits’</i></p> <p>Based on the level of understanding of this Programme, (such as the concept of certification, variations in Buying Company requirements and international regulations), additional review of these documents should be carried out to ensure understanding.</p> <p>Required documents:</p> <ol style="list-style-type: none"> i. Global Markets Programme - Overview ii. The Protocol: a description of progression through the Programme iii. The Checklist: two Excel versions, one for manufacturing and the other for primary production. These include comprehensive Assessor guidelines and the report form. iv. The Training and Competency Framework: guidance on training for companies.
2	Supplier capable for Self-Assessment?	<p>Does Supplier capability mean that help is needed to deliver a credible self-assessment? Credibility is dependent on the expertise of the individual leading the self-assessment.</p> <p>The supplier must determine whether they have the technical capability to conduct a credible self-assessment, based upon their level of expertise. If not, they may engage a service provider or other external qualified expert to conduct the self-assessment. The decision is to be taken by Supplier and/or Buying Company.</p>
3	Self-assessment carried out by a Service Provider.	<p>The Service Provider will undertake the self-assessment against the Basic or Basic and Intermediate Level Checklist.</p> <p>This step provides the Supplier with a gap analysis and the basis for a remedial action plan.</p> <p><i>Note: Users are encouraged to enter the ITC Standards Map GFSI Global Markets Programme Portal. They will be able to register their activity and use the specially designed self-assessment tool during Step One.</i></p>
4	Supplier carries out Self-Assessment	<p>A voluntary self-assessment by the Supplier against Basic and/or Intermediate Level Checklist.</p> <p>The scope of the self-assessment shall be the entire facility and all the manufacturing processes.</p> <p>This step provides the Supplier with a gap analysis and the basis for a remedial action plan.</p> <p><i>Note: Users are encouraged to enter the ITC Standards Map GFSI Global Markets Programme Portal. They will be able to register their activity and use the specially designed self-assessment tool during Step One</i></p>
5	Entry Level decision (Basic or Intermediate)	<p>The Self-assessment allows the Supplier and/or the Buying Company to decide the relevant entry level to the programme; whether the Supplier should pass to either Basic or Intermediate level assessment.</p> <p><i>Note: There may be legislation in certain countries that requires HACCP to be implemented. In such cases, all suppliers would have to start at Intermediate Level because HACCP is not included at Basic Level. However, Basic Level does include B.C 1 “Preliminary Tasks” which will start a supplier towards the implementation of a HACCP system.</i></p>

2.2. User Guidance (2/5)

Box	DESCRIPTION	USER GUIDANCE
6	Select Assessment Provider	Once the self-assessment has confirmed the relevant level for the Supplier, an Assessment Provider can be selected. There are two possible options for the selection of Assessment Providers: i. A Certification Body that is accredited to deliver a GFSI recognised food safety management scheme. ii. An Assessment Provider that has been specified by the relevant Buying Company.

2.2. User Guidance (3/5)

Box	DESCRIPTION	USER GUIDANCE
Assessment, Capacity Building and Continuous Improvement (1/2)		
7	Basic Assessment	<p>The Assessment Provider will carry out an assessment against the Basic level checklist.</p> <ul style="list-style-type: none"> • Duration, 1 working day, depending on size and complexity of operation, with any exemptions from particular requirements previously approved between the Supplier and Buying Company. • Time spent in production areas shall be no less than 65% of total assessment time, which includes interviews and observations. The Assessor is also encouraged to review documents within the production area rather than the office. • The Assessor will establish the Supplier's compliance against <u>each</u> clause. If nonconformances are identified, one of the following outcomes will be assigned: critical, major, minor and conform. • Critical nonconformances will result in an assessment failure. • Definitions of these outcomes are included in this protocol (see 2.3) and in the checklist. • This assessment does not consider outcomes of the self-assessment undertaken in Box 3 or 4.
8	Basic level: Report issued	<p>The report format, with scoring option, is included within the Excel checklist (Box 1). It is automatically generated from the Assessor comments against each clause. This report shall identify the status of the Supplier against the requirements listed in the checklist. It shall provide a description of nonconformances needing correction with timescales. The report shall be locked by the Assessment Provider who shall also retain the original copy. The locked report shall be provided to the Supplier and the Buying Company.</p>
9	Basic level achieved?	<p>Basic Level can only be achieved once all major nonconformances have been verified by the Assessor as being closed. In the event of critical nonconformances being raised during the assessment, a full repeat assessment should be carried out. The requirements of Buying Companies will vary because there is a customised report which allows them to identify certain clauses which they do not require. This may mean that certain clauses may be exempted. However, assessments are to be undertaken against all clauses. All nonconformances shall be reviewed and closed at the next assessment.</p> <p><i>Note: Users that have entered the ITC Standards Map GFSI Global Markets Programme Portal will have been able to register their activity at self-assessment stage. On achievement of Basic Level, they can update their record. Each year that they continue with assessments against the Global Markets Programme they can continue to update their record. This voluntary information is analysed by GFSI to understand Programme usage.</i></p>
10	Implement training and mentoring	<p>If Basic level has not been achieved, training and mentoring should be undertaken by the Supplier to ensure understanding of requirements and implementation of suitable and sustainable actions. Comprehensive guidance is provided in the "Training and Competency Framework" (Box 1).</p>
11	Corrective action plan implemented and verified.	<p>The Supplier should implement agreed corrective actions to enable progress to achieve Basic Level. Verification shall be by the Assessment Provider. Timelines may be set by the Assessment Provider with reference to the Buying Company and the Supplier. This will vary according to whether the nonconformance is critical, major or minor.</p>

2.2. User Guidance (4/5)

Box	DESCRIPTION	USER GUIDANCE
12	Intermediate Level requested?	The Programme is designed to allow a Supplier to move progressively towards achieving full certification. However, for certain markets and according to Buying Company requirements, some Suppliers may stay at Basic Level.
13	Re-assessment every 12 months	To maintain Basic or Intermediate Level, an assessment should be repeated at least every 12 months.
14	Intermediate assessment (same as Box 7)	<p>The Assessment Provider will carry out an assessment against Basic and Intermediate Level checklists.</p> <ul style="list-style-type: none"> • Duration, 1 working day, depending on size and complexity of operation, with exceptions approved between both parties (Supplier and Buying Company) • Time spent in production areas shall be no less than 65% of total assessment time, which includes interviews and observations. The Assessor is also encouraged to review documents within the production area rather than the office. • The Assessor will establish the Supplier's compliance against <u>each</u> clause. If nonconformances are identified, one of the following outcomes will be assigned: critical, major, minor and conform. • Critical nonconformances will result in an assessment failure. • Definitions of these outcomes are included in this protocol (see 2.3) and in the checklist. • This assessment does not consider the self-assessment undertaken in Box 3 or 4.
15	Intermediate level: Report issued (same as Box 8)	<p>The report format, with scoring option, is included within the Excel checklist (Box 1). It is automatically generated from the Assessor comments against each clause. This report shall identify the status of the Supplier against the requirements listed in the checklist.</p> <p>It shall provide a description of nonconformances needing correction with timescales.</p> <p>The report shall be locked by the Assessment Provider who shall also retain the original copy.</p> <p>The locked report shall be provided to the Supplier and the Buying Company.</p>
16	Intermediate level achieved? (same as Box 9)	<p>Intermediate Level can only be achieved once all major nonconformances have been verified by the Assessor as being closed. In the event of critical nonconformances being raised during the assessment, a full repeat assessment should be carried out. The requirements of Buying Companies will vary because there is a customised report which allows them to identify clauses which they do not require. This exemption choice has been limited to just two clauses for allergens and food defence. However, assessments are to be undertaken against all and exempted clauses.</p> <p><i>Note: Users that have entered the ITC Standards Map GFSI Global Markets Programme Portal will have been able to register their activity at self-assessment stage. On achievement of Intermediate Level, they can update their record. Each year that they continue with assessments against the Global Markets Programme they can continue to update their record. This voluntary information is analysed by GFSI to understand Programme usage.</i></p>
17	Implement training and mentoring (same as Box 10)	If Intermediate level has not been achieved, training and mentoring should be undertaken by the Supplier to ensure understanding of requirements and implementation of suitable and sustainable actions. Comprehensive guidance is provided in the "Training and Competency Framework" (Box 1).

2.2. User Guidance (5/5)

Box	DESCRIPTION	USER GUIDANCE
18	Corrective action plan implemented and validated. (same as Box 11)	The Supplier should implement agreed corrective actions to enable progress to achieve Intermediate level. Validation shall be by the Assessment Provider. Timelines may be set by the Assessment Provider with reference to the Buying Company and the Supplier. This will vary according to whether the nonconformance is critical, major or minor.
19	Proceed to Certification to GFSI recognised scheme?	The Programme is designed to allow a Supplier to move progressively towards achieving full certification. However, for certain markets and according to Buying Company requirements, some Suppliers may stay at this stage.
20	Certification	All the necessary information on how to achieve certification to a GFSI recognised scheme is available and can be downloaded free of charge from www.mygfsi.com .

2.3. Nonconformance Definitions

Background

The Assessor will classify nonconformance as Critical, Major and Minor. This will directly impact the site's result whether 'pass/fail' or 'score' option is chosen by the 'Buying Company' reviewing the assessment report.

Critical Nonconformance – Unacceptable

Affects food safety or regulatory compliance directly.

A finding is rated Critical when the factors related to that requirement are not met and as a result the product will be unsafe and/or does not meet regulation.

Note: A Critical Nonconformance will result in a failed assessment.

Major Nonconformance – May affect food safety.

A finding is rated Major when the factors related to that requirement are not met and as a result the product may be unsafe or present an increased food safety risk.

Minor Nonconformance – Is not likely to affect food safety.

A finding is rated Minor when the factors related to that requirement are not met and as a result the product is not likely to be unsafe or present an increased food safety risk.

Conform – Fully meeting a requirement.

Not Applicable (N/A)

When the Assessor decides a specific requirement is not applicable for a company, the assessor shall mark as "N/A" and provide a short explanation/justification in the comments section. For example, a company does not handle allergens therefore the requirements for allergen control do not apply.

Note: the use of N/A as an answer should only be used in agreement with the Buying Company.

2.4. Exemptions

- a. This worksheet option is provided for use by the Buying Company only.
- b. If no exemption is selected then the Assessor must answer all questions.
- c. Due to variations in legislation, for certain international markets there are two Checklist Items that may be exempted by the Buying Company. These are Items B.C. 2 (Control of allergens) and I.C. 4 (Food defence).
- d. If an exemption is selected, the Item will be highlighted in grey in the Checklist. The assessor will be advised that the item has been exempted and should not make any decisions in Column D.
- e. The scoring system shall be adjusted accordingly.

2.5. Scoring System

- a. All major and minor nonconformances are listed in the “Summary and Report” section of the Checklist.
- b. Criticals count as a 100 point deduction, Majors as 10 points and Minors as 2 points.
- c. There is a calculation against the number of clauses assessed to provide a numerical point score, not a percentage.
- d. In the event of a Critical or excessive Majors, the score can be zero.
- e. Unless set by the Buying Company, there will be no 'pass/fail' except in the event of a Critical nonconformance.
- f. The Excel assessment form has been automated using Excel formulae to deliver this system.
- g. The Excel Checklist document also provides a Conformance Overview worksheet which shows against which items nonconformances have been identified during the assessment.

2.5.1. Frequently Asked Questions about scoring system

Q1	Why is there a zero score when a number of the elements have been marked as compliant?
A1	<p>This is not a percentage system.</p> <p>When this system was defined by the Technical Working Group two things were agreed:</p> <ol style="list-style-type: none"> a. The importance of a major nonconformance (10 points) must be stressed with a factor of 5 times more than a minor (2 points). b. Any clause (there are 65 in Basic and a further 48 in Intermediate) can be found to have nonconformance classified by the Assessor as critical, major and minor. <p>Hence, when deductions exceed the allowance of the scoring system, it is possible to get down to a zero score during the assessment at a manufacturing site with multiple problems. It is also possible to get to zero with just one critical.</p> <p>It does not allow for a negative score.</p>
Q2	When I’m being assessed for intermediate, I can see that all of Basic is also assessed. The scoring system seems to allow me to pass Intermediate and fail Basic. How can this be correct?
A2	<p>First of all, the concept of ‘pass and fail’ is decided by the Buying Company.</p> <p>The two levels are scored separately. The only way to achieve Intermediate is to be compliant at Basic level.</p> <p>In the event that you ‘pass’ Intermediate and fail Basic, you will <u>not</u> have achieved Intermediate level, which requires compliance at both.</p> <p>However, there is a reverse situation where you pass Basic but are found not to be compliant at Intermediate.</p> <p>Decisions on how such situations are to be managed by the Buying Company.</p>
Q3	Do I have to use the scoring system?
A3	<p>We asked users what they thought of the previous approach. The key learning was that for entry-level suppliers ‘failure’ resulted in demotivation. Therefore, this new scoring system is an optional extra for Buying Companies. They may decide not to switch on this functionality. For those that decide not to use the scoring system, they will also have the colour coded conformity overview.</p>

2.5.2. Frequently Asked Questions: ITC Standards Map

Q1	Why is the GFSI Global Markets Programme, which is not a standard, included on an international platform with many standards?
A1	The ITC Standards Map includes a broad range of standards. With the inclusion of the GFSI Global Markets Programme it also includes a free access assessment process with no governance. In spite of the name, the ITC Standards Map is not just about standards.
Q2	I'm involved with a version of the GFSI Global Markets Programme which is run by a GFSI recognised scheme. Would you still advise that I use the ITC Portal and record my self-assessment and subsequent progress?
A2	The GFSI Global Markets Programme is not a standard. Use of the ITC portal is not a requirement. However, GFSI hopes that most users will record their work and achievements in the ITC Portal so that usage data can be gathered.



3. MANUFACTURING REVIEW 2015 – 2ND EDITION – CHANGE SUMMARY

This part of the document has been prepared to inform practitioners about the changes that they will find in the documents for the Second Edition of the manufacturing scope for the Global Markets Programme.

3.1. Background

The GFSI Global Markets Programme seeks to build food safety capacity for small and/or less developed businesses due to one or more of the following challenges: size, lack of technical expertise, economic resources or nature of the work. The Programme is open access and is not accredited. There is no certification.

The GFSI Global Markets Technical Working Group has concluded its mandate to revise the manufacturing scope, comprising the protocol, checklist and the training guidance and competency framework. This document summarises the resulting changes between First and Second Edition

3.2. Protocol: second edition

1. There is recognition that the Programme has become a “pathway to market access and certification” rather than a “pathway to certification.” The consultation process has shown that for many businesses with local supply chains and customers, unaccredited Basic or Intermediate level will be adequate. However, major suppliers and all those involved in export should aspire to achieve certification to a GFSI recognised standard.
2. The flowchart that guides users through the Programme has been simplified with new user guidance developed for assessors to drive consistency.
3. In the First Edition, a number of clauses had been pre-positioned as immediate ‘major’ nonconformances.
 - a. All pre-positioning has been removed.
 - b. Every clause would be assessed by one of these: Meets requirement, Minor, Major and Critical.
 - c. To move up from 'Basic' to 'Intermediate', a Supplier must have closed any Major NCs, verified by their Assessor.
4. There are new definitions of nonconformance:
 - a. Critical Nonconformance - Affects food safety or regulatory compliance directly.
 - b. Major Nonconformance – May affect food safety.
 - c. Minor Nonconformance – Is not likely to affect food safety.
 - d. Conform – Fully meeting a requirement.
5. The scoring system has been developed to allow for flexibility and adaptation in different markets. Buying Companies may choose to use it or not. Unless set by the Buying Company, there will be no 'pass/fail' except in the event of a Critical nonconformance. Customisation options in the checklist allow the Buying Company to turn on the scoring system and to set a pass score if required.
6. Due to variations in legislation, for certain international markets there are two Checklist Items that may be exempted by the Buying Company. These are Items B.C. 2 (Control of allergens) and I.C. 4 (Food defence).

3.3. Checklist: Second edition

Note to Practitioners: *The checklist is not a standard, there is no audit process or auditors involved and the listed items are to be assessed, not audited. There is no governance and no central record keeping. No certificate can be issued because there is no accreditation process for the Assessors.*

1. The percentages for Edition 2 against the GFSI Guidance Document have been calculated as 35%=Basic, 65%=Intermediate.
2. A full overview of Edition 1 and 2 is provided in Section 5 of this document.
3. Within Basic: revised:
 - a. Control of food hazards – ‘Preliminary tasks’: a specific description of a pre-requisite programme approach.
4. From Basic to Intermediate: moving requirements up:
 - a. Traceability: there are now requirements at both levels.
 - b. Incident Management: there are now requirements at both levels.
 - c. Allergens: there are now requirements at both levels.
5. From Intermediate to Basic: moving requirements down:
 - a. Management Responsibility: there are now requirements at both levels.
 - b. Record-keeping requirements: there are now requirements at both levels.
 - c. Control of measuring and monitoring equipment: there are now requirements at both levels.
 - d. Training: there are now requirements at both levels.
 - e. Staff facilities.
 - f. Waste management.
 - g. Storage and transport: there are now requirements at both levels.
6. The worksheet, which has a good level of functionality, has comprehensive advice in a worksheet titled: “How to use this document”.
7. Comprehensive user guidance has been developed to explain to assessors and individuals in businesses what each requirement means, against the following questions:
 - a. What does it mean?
 - b. What do I need to do?
 - c. What will the assessor do?
8. Supplementary guidance has been developed against selected clauses, such as in the section on HACCP.

3.4. Training and Competency Framework: new document

This framework has been developed to provide guidance on good practice for delivering training for food companies that are implementing the GFSI Global Markets Programme.

The document is in two sections:

1. Guidance on the development and delivery of training. This defines the roles and responsibilities of companies, training providers and individual learners in the training and learning process, as they relate to the Global Markets Programme.
2. The competencies required to achieve the GFSI Global Markets Programme Basic and Intermediate Levels.

3.5. Detailed Clause Overview: Edition 1 versus Edition 2 (1/2)

Basic: Edition 1		Intermediate: Edition 1	
A: Food safety management systems			
B.A.1	Specifications including product release	I.A.1	Management responsibility
B.A.2	Traceability	I.A.2	General documentation requirements
B.A.3	Food safety incident management	I.A.3	Procedures
B.A.4	Control of nonconforming product	I.A.4	Complaint handling
B.A.5	Corrective action	I.A.5	Control of measuring and monitoring devices
		I.A.6	Product analysis
		I.A.7	Purchasing
		I.A.8	Supplier approval and performance monitoring
		I.A.9	Training
B. Good Manufacturing Practices			
B.B.1	Personal hygiene	I.B.1	Facility and equipment
B.B.2	Facility environment	I.B.2	Staff and facilities
B.B.3	Cleaning and disinfection	I.B.3	Waste
B.B.4	Product contamination control	I.B.4	Storage and transport
B.B.5	Pest control		
B.B.6	Water quality		
C. Control of food hazards			
B.C.1	Control of food hazards-general and specific	I.C.1	HACCP
B.C.2	Control of allergens	I.C.2	Food defence

3.5. Detailed Clause Overview: Edition 1 versus Edition 2 (2/2)

Basic: Edition 2		Intermediate: Edition 2	
A. Food Safety Management Systems			
B.A.1	Specifications including product release		
B.A.2	Traceability	I.A.2	Traceability
B.A.3	Food safety incident management	I.A.3	Food safety incident management
B.A.4	Control of nonconforming product		
B.A.5	Corrective action		
B.A.6	Management responsibility	I.A.6	Management responsibility
B.A.7	Record-keeping requirements	I.A.7	General documentation requirements
B.A.8	Control of measuring and monitoring equipment	I.A.8	Control of measuring and monitoring equipment
B.A.9	Training	I.A.9	Training
		I.A.10	Procedures
		I.A.11	Complaint handling
		I.A.12	Product analysis
		I.A.13	Purchasing
		I.A.14	Supplier approval and performance monitoring
B. Good Manufacturing Practices			
B.B.1	Personal hygiene		
B.B.2	Facility environment		
B.B.3	Cleaning and disinfection		
B.B.4	Product contamination control		
B.B.5	Pest control		
B.B.6	Water quality		
B.B.7	Staff facilities		
B.B.8	Waste management		
B.B.9	Storage and transport	I.B.9	Storage and transport
		I.B.10	Facility and equipment maintenance
C. Control of food hazards			
B.C.1	Preliminary tasks		
B.C.2	Control of allergens		
		I.C.3	HACCP
		I.C.4	Food Defence

Appendix

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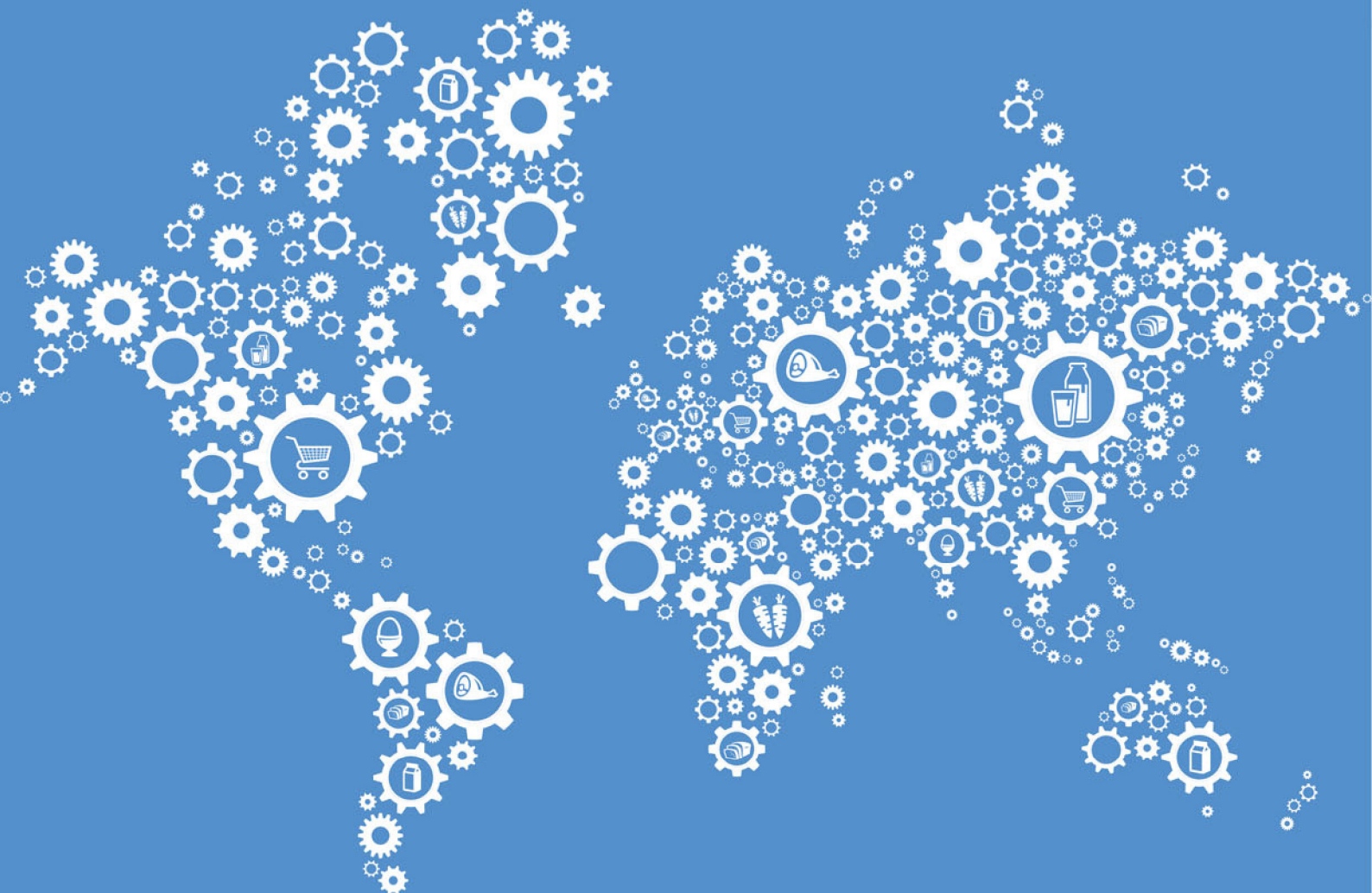
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