

# **BRCGS Gluten-Free**

GFCP Issue 3 Auditor Checklist and Site Self-Assessment Tool

# 1 Senior leadership commitment

Clause	Requirements	Conforms	Comments
1.1	The site's senior leadership shall ensure that the site's GFMS conforms with all the requirements identified in the GFCP Global Standard.  The site's senior leadership shall demonstrate a commitment to their GFMS by:  • providing the necessary resources and the time required for the development, implementation, and effective maintenance of the GFMS and for the training of appropriate staff in their area(s) of responsibility  • providing the financial resources to ensure that the construction of the premises, its internal fittings, the installation of the equipment, the maintenance of the premises and equipment, as well as the supplies required to perform the above, meet all applicable regulatory and program requirements and support the implementation and effectiveness of the GFMS  • designating personnel with defined responsibilities and the authority to initiate, implement, and record corrective actions  • communicating to employees the importance of meeting the requirements of the site's GFMS, including any regulatory requirements related to product safety and gluten control, and the importance of reporting problems to the identified person(s); designating personnel, with authority, to enforce conformity of the product safety procedures identified in the site's GFMS for any person entering or working within the site		



	fostering the continuous improvement of the GFMS to ensure its effectiveness by: validating control measures, making changes to the system as a result of corrective actions or reassessment activities, and ensuring active participation in GFMS team meetings     providing sufficient time for GFMS team meetings.	
1.2	The site's leadership team shall ensure all information and documentation is accessible during evaluation processes and subsequent verification/audit activities.	
1.3	The site shall have a documented policy that confirms:  • the senior leadership's full support for developing, implementing, and maintaining an effective GFMS  • the site's commitment to producing product in conformity with all requirements of the GFCP Global Standard.  The policy shall be signed and dated by a representative of the senior leadership at the site with authority to ensure adherence to responsibilities described in this section. The policy shall be renewed on an annual basis and when the senior leadership representative is replaced. The policy must be communicated to all staff.  Note: The policy may be combined with an equivalent policy as part of another food safety management system.	
1.4	Senior leadership shall appoint a GFMS team leader who, irrespective of other responsibilities, shall have the responsibility and authority to:  ensure that the GFMS is developed, validated, periodically reviewed, implemented, and maintained  be the main contact with designated staff and auditors.	

	The GFMS team leader must be trained in, have an in-depth knowledge of, and show competence in the GFMS principles.  The GFMS team leader must have taken and passed the GFCP industry training course, or an equivalent course that is acceptable to BRC Global Standards.	
1.5	The GFMS team shall be multidisciplinary and must include those responsible for quality/technical, product development, sanitation and hygiene, production operations, engineering/maintenance, and other relevant functions.  The team members shall have specific knowledge of gluten control and relevant knowledge of product, process, marketing claims, and associated hazards.  External expertise may be used, but day-to-day management of the food safety system shall	
1.6	remain the responsibility of the site.  The GFMS team shall meet at appropriately planned intervals, annually at a minimum, to discuss, among other points:  action plans and timeframes from previous GFMS team meeting reviews  changes in the GFMS  results of internal, second-party, and/or third-party GFMS audits  customer complaints and results of any customer feedback  incidents (including both recalls and withdrawals), corrective actions, out-of-specification results, and nonconforming materials  reviews of the effectiveness of the GFMS  resource requirements.  The frequency of meetings must be sufficient to manage the risks associated with the topics covered and may be increased depending on circumstance.  Records of the meeting shall be documented. The decisions and actions agreed within the review process shall be effectively	



communicated to appropriate staff, and actions implemented within agreed timescales.	
A member of the senior leadership team must attend, at a minimum, one GFMS team meeting annually.	

## 2 Prerequisite programs

Clause	Requirements	Conforms	Comments
2.1	The site shall have fully implemented environmental and operational programs (prerequisite programs) in place. These must include, but are not limited to the following:		
	• premises		
	<ul><li>purchasing</li></ul>		
	<ul> <li>transportation, receiving, shipping, and storage</li> </ul>		
	<ul> <li>equipment and maintenance</li> </ul>		
	<ul> <li>personnel and training</li> </ul>		
	• sanitation		
	• pest control		
	<ul> <li>traceability, recall and withdrawal</li> </ul>		
	allergen controls.		
	The control measures and monitoring procedures for the prerequisite programs must be clearly documented and included within the development and reviews of the GFMS.		



## **3** Gluten controls

3.1	3.1 Gluten awareness training		
Clause	Requirements	Conforms	Comments
3.1.1	A documented gluten awareness training program must be in place and training activities documented. Documentation must include training materials, training records, and competency assessment.  All relevant personnel, including engineers/maintenance, temporary staff, and contractors, shall have received general gluten awareness training and be trained in the site's gluten-handling procedures.  Training shall include, at a minimum, where appropriate:  • gluten-related disorders, symptoms, and reactions  • ingredients and types of foods that contain gluten  • traffic patterns of people and equipment  • high risk gluten-free production areas  • uniforms and personal protective equipment  • job rotation practices  • management of contractors, visitors, and temporary employees.		
3.2	Product development		
Clause	Requirements	Conforms	Comments
3.2.1	Procedures and/or policies shall be developed and implemented to ensure adequate control of new or modified product formulations. This must include a minimum of:  • a product development and approval process flow, including steps to be followed when modifications to existing product formulations are made  • communication links among all the steps in the chain of production once a new formulation or changes in a formulation have been approved  • a requirement for the product development and approval process to include review and agreement by the GFMS team leader.		

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3.3	3.3 Supplier approval, purchasing, and incoming ingredients and inputs			
Clause	Requirements	Conforms	Comments	
3.3.1	Procedures and/or policies related to purchasing of ingredients and inputs shall be developed and implemented to ensure:  • proper control and identification of gluten  • that all ingredients and inputs intended to be rendered gluten-free by a production process are validated using appropriate methodology and testing  • that all gluten-free ingredients and inputs that have been rendered gluten-free by a production process have been validated using appropriate methodology and testing.  Use of ingredients which have been rendered gluten-free through a validated process must be acceptable to BRC Global Standards.  The site shall undertake a documented risk assessment of all ingredients and inputs to identify potential gluten sources (including hidden gluten sources of contamination). The risk assessment shall form the basis for the gluten-free ingredients and inputs acceptance as well as for the testing procedure and processes adopted for supplier approval and monitoring.  The risk assessment for gluten-free ingredients and	Conforms	Comments	
	<ul> <li>inputs must be current and shall be updated, at a minimum, when:</li> <li>there is a change in gluten-free ingredients and inputs, gluten-free ingredients and inputs, processing, or the supplier of the gluten-free ingredients and inputs</li> <li>a new risk of gluten contamination emerges</li> <li>there is a product recall or withdrawal in which a specific gluten-free ingredient or input is implicated.</li> </ul>			
3.3.2	The site shall have a documented supplier approval procedure to ensure that all suppliers and emergency suppliers of ingredients and inputs effectively manage gluten contamination risks and are operating effective traceability processes. The approval procedure shall include, at a minimum:			



- a valid certificate of recognition to show that the site conforms to the GFCP Global Standard.
   The gluten-free ingredient or input must be listed on the supplier's Schedule A or
- a valid certificate from a gluten-free supplier certification program recognized by BRC Global Standards or
- all of the following:
  - a supplier questionnaire, with a scope that includes gluten control, product safety, traceability, HACCP review, and good manufacturing practices, that has been reviewed and verified by a demonstrably competent person and member of the GFMS team
  - an allergen questionnaire that includes questions about gluten content and identifies the gluten status of each ingredient or input
  - the supplier's specification for each ingredient, ingredient blend, and components of ingredient blends (as applicable), clearly listing each ingredient and, where applicable, components of ingredients. Specifications must be reviewed and agreed on by a member of the GFMS team
  - documentation (e.g., letter of guarantee) indicating that the supplier shall: meet the site's specifications; notify the site when a change is made to their ingredient blend formula; and confirmation that such changes will not be made without prior approval from the site.

Additional items that would support and strengthen the approval process are:

- second- or third-party gluten-free audit and certification
- certificates for other food safety schemes
- a robust risk-based ingredient testing and scheme/plan.

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	Note: Grain handling and processing companies must also meet the requirements set out in Appendix 4. Companies buying grain and grain-based ingredients may use the requirements in Appendix 4 as a tool to assess their suppliers of these ingredients.	
3.3.3	There shall be a documented process for ongoing supplier performance review, based on risk and using defined performance criteria. Records of the review and actions taken as a result of the review shall be kept.	
3.3.4	The site shall have an up-to-date list or database of approved suppliers. This may be on paper (hard copy) or it may be controlled on an electronic system. The list or applicable components of the database shall be readily available to relevant staff (e.g., at goods receipt).	
3.3.5	The site shall have a procedure for the acceptance of incoming ingredients and inputs on receipt, based upon the risk assessment, and must consider:  • sampling and testing  • visual inspection on receipt  • certificates of analysis for gluten from an accredited laboratory – specific to each consignment  • certificates of analysis for gluten, from suppliers that have used an approved method (as per Appendix 5) that has been validated in-house. Validation must include participation in a proficiency testing program, through an accredited proficiency test provider  • any other means necessary to satisfy the risk assessment.  A list of incoming ingredients and inputs and the requirements to be met for acceptance shall be available. The parameters for acceptance and frequency of testing shall be clearly defined, implemented, and reviewed.	
3.3.6	Procedures shall be in place to ensure that approved changes to ingredients and inputs, or of suppliers, are communicated to goods receipt personnel and that only the correct version of the ingredient and inputs is accepted (for example,	
	when labels or printed packaging have been	

Commented [MS(G1]: 'ensure' stated at beginning of sentence.



amended). Only the correct version shall be released into production. 3.4 Approval and control of labels Clause Requirements Conforms Comments 3.4.1 Where applicable, procedures and/or policies shall be developed and implemented to ensure proper control of new or modified labels. This must include a minimum of: a label approval process that includes steps to be followed in case of re-approval of product labels following modifications to existing product formulations the documentation of the communication links between all the steps in the chain of production following approval of a new label or changes to physical comparison of received labels to approved labels confirmation that externally printed labels meet the specifications agreed on between the printer and the site. Where applicable, procedures and/or policies concerning labels shall be developed and implemented to ensure that the labels of approved ingredients received match the site's finished product list of ingredients and components of ingredients. Where applicable, procedures related to labeling of finished product shall be developed and implemented to ensure that the finished product label information accurately represents the product name and the composition of the product on which the label is affixed. Where the label information is the responsibility of a customer or a nominated third party the company shall provide: information to enable the label to be accurately updates whenever a change occurs that may affect the label information. 3.5 **Marketing claims** Clause Requirements Conforms Comments

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3.5.1	Use of GFCP and other third-party trademarks or statements on labels, advertising, marketing, and communication material (whether in print or digital/online) must be:  • approved by BRC Global Standards  • in compliance with the GFCP Trademark Usage Guide and/or the requirements of the owner of the trademark or statement  • in compliance with the legislation of the country where the product will be sold.  Any reference to "certification" shall be limited to the site and/or the GFMS that is delivered there. There shall not be any reference to "product certification."		
3.6	Finished product specifications		
Clause	Requirements	Conforms	Comments
3.6.1	Accurate and up-to-date specifications shall be available for all finished products. These may either be in the form of a printed or electronic document or part of an online specification system.  They shall include key data to meet customer and legal requirements and assist the user in the safe usage of the product.		
3.7	Contamination control		
Clause	Requirements	Conforms	Comments
3.7.1	Where applicable, and based on risk, the procedures and/or policies shall be developed and implemented to control substitutions and crosscontamination of undeclared gluten sources in the		



	<ul> <li>dedicated or segregated storage of ingredients containing gluten sources</li> <li>the identification and sanitation of bulk containers housing a gluten source or ingredients containing gluten sources</li> <li>dedicated utensils, equipment and areas used to handle gluten sources</li> <li>the handling and storage of rework product(s) containing ingredients that are gluten sources</li> <li>the use of equipment, tools, and utensils with sound sanitary design</li> <li>the cleaning of equipment/product contact surfaces/areas during operations if dedicated lines/equipment/areas for gluten sources are not available</li> <li>dedicated maintenance and engineering tools</li> <li>appropriate airflow</li> <li>the control and separation of ingredients that are used in both gluten-free and gluten-containing production.</li> </ul>		
3.8	Work in progress		
Clause	Requirements	Conforms	Comments
3.8.1	Where applicable, procedures associated with weighing/blending/mixing/formulation shall be developed and implemented to ensure that the correct ingredient is added to the correct product as indicated in the formula.		
3.8.2	Where applicable, procedures and/or policies related to the use of rework shall be developed and implemented to prevent the introduction of gluten into a gluten-free product, and to ensure that the rework formulation ingredients and the product formulation ingredients are compatible, including		
	their appropriate designation (e.g., labeling).		
3.9	Segregation and disposal of obsolete and v	vaste mat	erial
3.9 S		vaste mat	erial  Comments

3.10	trademark) or risk of cross-contamination. Obsolete materials include:  • labels (refers to any preprinted packaging that bears a list of ingredients)  • ingredients and work in progress  • finished products.  aboratory and testing		
Clause	Requirements	Conforms	Comments
3.10.1	A sampling and gluten-testing program must be developed and implemented as part of an overall program to validate and verify control of cross-contamination of undeclared gluten sources in ingredients and finished products. All manufacturers must evaluate their risk of contamination with gluten before they start developing a sampling program for all incoming materials and for each processing step (including cleaning and sanitation), following the guidelines and risk assessment tools outlined in Appendix 5. The objective is to ensure that the finished product meets regulatory requirements (e.g., not more than 20 ppm of gluten) or a lower limit imposed and advertised by the site (e.g., <5 ppm or undetectable).		
3.10.2	An accredited laboratory must be used annually (at a minimum) to validate the site's internal or contracted testing practices.  The laboratory must have ISO 17025 accreditation from a competent authority, methods for gluten testing must fall within the scope of their accreditation, and the methods for the applicable matrix must have been fully validated at their site.		
3.11	Complaint handling		
Clause	Requirements	Conforms	Comments
3.11.1	All complaints shall be recorded. Where sufficient information is provided, complaints shall be investigated and the results of that investigation recorded. Actions appropriate to the seriousness and frequency of the problems identified shall be carried out promptly and effectively by appropriately trained staff.  As soon as reasonably possible, the site should notify BRC Global Standards of any complaint about		



	a gluten-free product that suggests it has a high		
	probability of failing to comply with the		
	requirements of the GFCP Global Standard.		
3.12 I	Recall		
Clause	Requirements	Conforms	Comments
3.12.1	The site shall notify the national, regulatory competent authority, certification body, and BRC Global Standards of any recalls or withdrawals related to a gluten-free product. Notification to BRC Global Standards must be within 24 hours from the date of release of the official recall or withdrawal notice.  Effectiveness of the recall plan must be tested on one gluten-free product at least once a year.		

# 4 HACCP principles

Clause	Requirements	Conforms	Comments
4.1	The company shall have a fully implemented and effective food safety plan incorporating the Codex Alimentarius HACCP principles:  Assemble the team  Describe the product and identify its intended use (e.g. gluten-free)  List product ingredients and incoming material  Construct a process flow diagram and confirm its accuracy  Construct a plant schematic and confirm its accuracy  Identify and analyze hazards (HACCP Principle 1)¹  Determine critical control point(s) (CCP) and other control measures (i.e. process control (PC) and prerequisite programs (PP)) (HACCP Principle 2)  Establish critical limits (HACCP Principle 3)  Establish monitoring procedures (HACCP Principle 4)  Establish deviation procedures (HACCP Principle 5)  Establish record keeping (HACCP Principle 7)  All relevant information needed to conduct the preliminary steps, the hazard analysis, and the determination of the CCPs and process controls shall be documented, updated whenever there are changes, and included within the development and reviews of the GFMS.		

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 $<sup>^{\</sup>rm 1}$  Note: It is mandatory that gluten is identified as a hazard.



#### **5** Records

Clause	Requirements	Conforms	Comments
5.1	Records shall be kept to demonstrate the effective application of the control measure and to facilitate official verifications by the BRC Global Standards approved auditor or other competent authority.  Records shall be established to document:  the monitoring results, including, when necessary, the recording of quantifiable values as prescribed in the control measures  all information and actions taken in response to a deviation identified as a result of monitoring and verification  the verification results.		
5.2	Records must be up-to-date, legible, accurate, in good condition, and retrievable. Any alterations to records shall be authorized and justification for alteration shall be recorded. Where records are in electronic form these shall also be:  • suitably backed up to prevent loss  • stored securely (e.g., authorized access, control of amendments, password protected)  • auditable (capture name, date, etc.).		
5.3	Records shall be retained for a defined period with consideration given to:  any legal or customer requirements  the shelf life of the product.  This shall take into account, where it is specified on the label, the possibility that shelf life may be extended by the consumer (e.g., by freezing).  As a minimum, records shall be retained for the shelf life of the product plus 12 months.		

## **6 Document control**

Clause	Requirements	Conforms	Comments
6.1	The site shall have a procedure to manage documents that form part of the GFMS. This shall include:		
	a list of all controlled documents, indicating the latest version number		
	the method for the identification and authorization of controlled documents		
	a record of the reason for any changes or amendments to documents		
	the system for the replacement of existing documents when these are updated.		
	Where documents are stored in electronic form these shall also be:		
	<ul> <li>stored securely (e.g., authorized access, control of amendments, password protected)</li> <li>backed up to prevent loss.</li> </ul>		



## 7 Validation

Clause	Requirements	Conforms	Comments
7.1	Control measures must be validated. Validation documentation must include, but is not limited to:  scientific, technical, or regulatory support to prove effective control of the hazard  supporting data to demonstrate that the monitoring procedures are effective enough to detect loss of control at a control point before the finished product leaves		
	The approved auditor may request validation documentation for novel control measures covered by prerequisite programs that have an immediate impact on gluten control (e.g., new technology for testing).  For more information on the validation process, BRC Global Standards recommends the Guidelines for the Validation of Food Safety Control Measures developed by the Codex Alimentarius Committee.		

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## 8 GFMS maintenance and reassessment

Clause	Requirements	Conforms	Comments
8.1	The GFMS team shall review the GFMS at least annually and prior to any changes that may affect product safety (gluten specifically). As a guide, these may include issues such as:  • change in gluten-free materials or in a supplier of gluten-free materials  • change in ingredients/recipe  • change in processing conditions, process flow, or equipment  • change in packaging, storage, or distribution conditions  • emergence of a new risk (e.g., known adulteration of an ingredient or other relevant, published information, e.g., a recall of a similar product)  • changes required following a recall or withdrawal  • new developments in scientific and/or regulatory information associated with ingredients, process, or product  • noncompliance identified during monitoring and verification activities  • consumer/client complaints  • nonconformities identified during GFCP Global Standard audits or surveys done by government agencies or the national, regulatory competent authority  • changes in production volume that impact on the product flow, sanitation schedule, employee training, etc.  Appropriate changes resulting from the review shall be incorporated into the GFMS, communicated through relevant training, fully	Conforms	Comments

**Commented [MS(G4]:** Change made to avoid repetition of 'appropriate'



#### 9 Internal audits

Clause	Requirements	Conforms	Comments
9.1	There shall be a scheduled program of internal audits. The frequency that each activity is audited within the scheduled program shall be established in relation to the risks associated with the activity and previous audit performance; all activities shall be covered at least once each year.  As a minimum, the scope of the internal audit program shall include:		
	<ul> <li>the GFMS, including the activities to implement the system (e.g., supplier approval, corrective actions, and verification)</li> <li>prerequisite programs</li> <li>procedures implemented to achieve the requirements of the GFCP Global Standard.</li> </ul>		
	Each internal audit within the program shall have a defined scope and consider a defined activity or section of the GFMS.  Internal audits shall be carried out by appropriately trained, competent auditors. Auditors shall be independent of, and avoid a conflict of interest with, the area they are auditing (e.g., they must not audit their own work).		
	The internal audit program shall be fully implemented. Internal audit reports shall identify conformity as well as nonconformity and include objective evidence of the findings.		
	The results shall be reported to the personnel responsible for the activity audited.		
	Corrective actions, preventive actions and timescales for their implementation shall be agreed and completion of the actions verified.		