BRCGS | Gluten Free

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GLUTEN-FREE CERTIFICATION PROGRAM

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BRCGS Food Safety

Gluten-Free Certification Program Global Standard

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1 BRCGS is a trading name of BRC Trading Ltd.

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Acknowledgements
A “thank you” from BRCGS

BRCGS would like to thank all the producers, manufacturers, distributors, retailers, health professionals, product specialists, and leading celiac organizations who participated in the development of this version of the GFCP Global Standard. This Standard draws heavily from materials and processes used by competent authorities, recognized worldwide, that promote the use of HACCP (Hazard Analysis and Critical Control Point) principles or the equivalent.

Definitions

accreditation	is an independent competence assessment of a certification body, performed by an accreditation body and whereby the management system assessed is based upon globally accepted international standards.
advertise	includes the making of a representation by any means for the purpose of promoting, directly or indirectly, the sale or disposal of a gluten-free product.
application	is the first step (performed online) for a new brand owner and manufacturer wishing to acquire recognition under the GFCP Global Standard.
approved auditor	means a person who has met the criteria of BRCGS and is approved to be an authorized auditor for the GFCP Global Standard.
audit	includes: • in respect of a process, the verification or monitoring of the process, and • the examination of the other information that may be necessary to verify conformance with the requirements of the GFCP Global Standard.
celiac disease	(also spelled coeliac disease) is a serious autoimmune disorder that can occur in genetically predisposed people where the ingestion of gluten leads to damage in the small intestine, which can in turn lead to long-term health complications. *See also* non-celiac gluten sensitivity.
certificate of recognition	is the official recognition given to a site that conforms to the GFCP Global Standard.
certification body	is a licensed entity which is authorized by BRCGS to provide and manage auditing services.
certified	means that a site and its overall GFMS have been assessed as conforming to the GFCP Global Standard requirements.
critical control point	means a point in a process at which control must be applied in order to prevent or eliminate a hazard or reduce a hazard to an acceptable level.
critical limit	means the minimum or maximum value to which a hazard must be controlled at a critical control point or equivalent to prevent or eliminate the hazard or reduce it to an acceptable level as may be determined by the national, regulatory competent authority.
drug	has the same meaning as defined by the national, regulatory competent authority where the product is sold.
food	has the same meaning as defined by the national, regulatory competent authority where the product is sold.
food additive	has the same meaning as defined by the national, regulatory competent authority where the product is sold.
gluten	is defined as a protein fraction (e.g., gliadins or glutenins) from wheat, rye, barley, oats[2] or their crossbred varieties and derivatives thereof, to which some persons are intolerant and that is insoluble in water and 0.5M sodium chloride.

2 Does not include verifiable gluten-free oats.

Gluten-Free Certification Program (GFCP) Global Standard	is the name for a set of standards and requirements which, when successfully implemented and verified, permit brand owners and manufacturing sites to market gluten-free assurances and claims to customers and consumers.
gluten-free management system (GFMS)	is the result of a Hazard Analysis and Critical Control Points (HACCP) assessment that is prepared in accordance with the requirements of the GFCP Global Standard for a process or product and that specifies, in respect of the process or product, all the hazards, critical control points, critical limits, monitoring procedures, deviation procedures, verification procedures, and records.
gluten-free product	shall be defined as any product that conforms to the GFCP Global Standard requirements.
HACCP	Hazard Analysis and Critical Control Points is a science-based risk management system with the objective of identifying and preventing, reducing or eliminating food safety hazards.
hazard	means a biological, chemical or physical agent or factor that has the potential to cause a product to be unsafe for human consumption or a failure to conform to the GFCP Global Standard in the absence of its control.
ingredient	is an individual unit of product that is combined with one or more other individual units of a product formulation to form an integral unit of product.
input	means a material which is not an ingredient but is, however, required to complete the manufacture of the product (e.g., processing aids, packaging, cleaning materials) and may contribute to gluten contamination of the product.
internal audit	is a conformity assessment conducted by the site as a requirement of the GFMS.
label	means any tag, brand, mark, pictorial or other descriptive matter that is written, printed, stenciled, marked, embossed or impressed on, or attached to, a container of food.
limit of detection	(LOD) The limit of detection is typically defined as the lowest concentration or quantity of a substance that can be reliably distinguished with a specific analytical method.
limit of quantification	(LOQ) The limit of quantification is the lowest concentration at which the analyte can be reliably detected but at which some predefined goals for bias and imprecision are met. The LOQ may be equivalent to the LOD or it may be a much higher or lower concentration.
list of certified sites	is the list of companies deemed to be in conformance with the GFCP Global Standard which is maintained by BRCGS.
matrix	refers to all components of a sample, with the exception of the analyte of interest (in this case, gluten) that can affect the testing result.
non-celiac gluten sensitivity	is a condition with gastrointestinal and/or extraintestinal symptoms that is triggered by gluten ingestion in the absence of celiac disease and wheat allergy.
prerequisite programs	are the written programs developed for a recognized site as applicable in accordance with BRCGS to ensure compliance with the GFCP Global Standard. Such programs relate to: • the premises, including its outside property, buildings, and sanitary facilities • the quality of the water, ice, and steam • the storage and transportation of products, including temperature control and the vehicles for transporting products • the storage of material (e.g., incoming material, non-food chemicals, and finished products), including temperature control • the equipment, including its general design, installation, maintenance, and calibration • the training, hygiene, and health of personnel • sanitation and pest control • recall procedures and distribution records.

Program License Agreement (PLA)	is the official authorization to use and apply the GFCP Global Standard trademark(s) or similar words.
recovery	is the process of finding the accurate quantity of targeted substance in a sample.
Schedule A	is a control and tracking document, listing all gluten-free products produced at a site and which are intended to display any of the GFCP Global Standard permitted trademarks.
spiking	is the process of adding a known amount of an analyte to a sample to confirm the performance of an analytical procedure.
validation	(in accordance with the Codex Alimentarius) is the process of obtaining evidence that a control measure, if properly implemented, is capable of controlling a particular hazard to the specified level.
verification	(in accordance with the Codex Alimentarius, and in addition to monitoring) is the application of methods, procedures, tests, and evaluations to determine whether a control measure is or has been operating as intended.

Abbreviations

ACSP	Accredited Container Sampler Program administrated by the Canadian Grain Commission
ANAB	American National Accreditation Board
AOAC	Association of Analytical Chemists
CCSP	Certified Container Sampling Program administrated by the Canadian Grain Commission
CGC	Canadian Grain Commission
CGSP	Canadian Grain Sampling Program administrated by the Canadian Food Inspection Agency Grains and Oilseeds Section
GFCP	Gluten-Free Certification Program
GFMS	gluten-free management system
GFSI	Global Food Safety Initiative
HACCP	Hazard Analysis and Critical Control Points
KPI	key performance indicator
LSSP	Licence Seed Sampler Program administrated by the Canadian Food Inspection Agency
PLA	Program License Agreement

Part I
The gluten-free management system

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The gluten-free management system

There is currently no cure for persons suffering from celiac disease or non-celiac gluten sensitivity or intolerance, nor is there any on the horizon. The only mitigation or treatment is a strict gluten-free diet (i.e., all foods must contain less than 20 ppm gluten, with the ideal being that none is detected), since more recent science indicates that mere avoidance of gluten for these persons is not enough. Foods coming out of sites and systems certified to the Gluten-Free Certification Program (GFCP) Global Standard will satisfy that essential need.

In Europe, Canada, and the USA, the mean frequency of celiac disease (CD) in the general population is approximately 1% and rising, with some regional differences. A similar disease prevalence has been found in other countries mostly populated by individuals of European origin, for example Australia and Argentina. CD is a common disorder in North Africa, the Middle East, and India, the highest CD prevalence in the world (5.6%) having been described in the Saharawi, who have Arab-Berber ancestry and originate from the area known as Western Sahara.

Non-celiac gluten sensitivity (NCGS) has recently been recognized by the scientific community as a gluten-related disorder and is defined as a condition with gastrointestinal and/or extraintestinal symptoms triggered by gluten ingestion in the absence of celiac disease and wheat allergy. The global prevalence is estimated to be 5% of the population. Currently, there is no specific serological marker, and non-celiac gluten sensitivity remains a diagnosis of exclusion from CD and wheat allergy. However, a gluten-free diet normally reduces the effects. CD exists in the population with a 1% prevalence; the relative levels of reaction to some common allergens are: shellfish (1.4%), tree nuts (1.2%), peanut (1.0%), and egg (0.6%). The estimated prevalence of CD plus NCGS at approximately 6% is comparable to that of all priority allergens combined, which is 7.5%. This is in the order of more than 60 million consumers requiring a gluten-free diet in Canada, USA, and Europe combined.

In classical CD and NCGS, patients have a variety of signs and symptoms, such as bloating, cramping, and diarrhea; anemia and chronic fatigue; and weight loss (or growth failure in children) as well as bone or joint pain. As stated above, there is no cure. The only mitigation option for those who are afflicted is to dedicate themselves to a 100% gluten-free diet, which is very difficult. Research has shown that without a gluten-free diet, the long-term effects can lead to very serious health consequences (e.g., severe neurological manifestations such as encephalopathy). In the case of encephalopathy, which is a broad term used to describe abnormal brain function or brain structure, the abnormality may be transient, recurrent, or permanent. The loss of brain function may be reversible, static and stable, or progressively worse with increasing loss of brain activity over time. One clinical study showed on average 73% of CD and NCGS patients had mild ataxia (serious motor effects but patient able to walk unaided), 16% moderate (patient needs walking aids/support to be able to walk) and 11% severe (patient uses a wheelchair). In the absence of a strict gluten-free diet, these consequences are virtually unavoidable.

Clearly, the GFCP Global Standard surpasses the status quo:

- which focuses on end-product testing for gluten when declared to be gluten-free, without proof of a functioning management system; and/or
- in which, celiac persons without supervision seeking out so-called inherently gluten-free products or avoiding gluten-containing ingredients as they appear on labels continue to suffer short-term and long-term debilitating effects.

Under the status quo, recent clinical studies measuring the amount of gluten consumed by people with CD who believed themselves to be on a gluten-free diet found that their fecal material contained significantly more than 200 mg of gluten per day. The scientific consensus is that the safe level for most of these persons is 10 mg of gluten per day, which is equivalent to 17 one-ounce servings of labelled gluten-free food containing just under 20 ppm of gluten. A contributing factor is that consumers fail to

correctly distinguish gluten-containing ingredients. A Canadian study has found that adults with CD who are trying to follow a gluten-free diet have difficulty choosing appropriate gluten-free foods based on product labeling information, leading to suggestions that explicit labeling that identifies gluten-free products may be helpful. Products displaying explicit GFCP Global Standard trademarks at the point of purchase assist consumers by removing the stress of drilling down through a complicated list of ingredients that the manufacturer might have changed without warning, possibly adding gluten to a previously trusted gluten-free product.

Scope of the GFCP Global Standard

The GFCP Global Standard applies only to the control of gluten in the manufacture, processing, and packing of gluten-free products. These include:

- processed foods, both own brand and customer branded
- ingredients for use by food service companies, catering companies, and food manufacturers
- pet foods
- cosmetics
- natural health products
- drugs.

Benefits of a gluten-free management system

The long-term outcome of the GFCP Global Standard is to promote a systems approach to prevent failures that could harm the public. Correctly applied, a site's gluten-free management system (GFMS) will provide a very strong level of protection from failure, and if failure does occur, it will enable the rapid identification and management of risks and deviations. Increasing the availability of gluten-free products that conform to regulatory requirements will enable market expansion and should, at the same time, reduce the burden on government enforcement. Consumers will benefit by having increased confidence in their purchases, wider availability, and variety of choice.

Responsibilities of BRCGS

- Develop and maintain a GFCP Global Standard in consultation with consumers, industry, and government stakeholders. Consideration will be given to harmonize with best approaches that have been developed and successfully implemented.
- Recognize the systems that conform to the requirements of the GFCP Global Standard.
- Verify the implementation, effectiveness, and maintenance of the GFMS that manufacturers and distributors have in place.
- Ensure competencies for the recognition and verification of the GFMS developed and implemented by sites.
- Ensure consistency of the evaluation and audit processes as well as the consistency of the verification of conformity.
- Provide the resources to enable the timely evaluation and administration of the GFCP Global Standard.
- Consider any information presented in the conduct of the GFCP Global Standard, such as copies of the GFMS documentation that are obtained by a BRCGS officer or auditor, to be private and confidential, and protect the information to the extent of the law. BRCGS will only request information which is relevant to the administration of the Standard.

Senior leadership commitment

Within a food business, food safety must be seen as a cross-functional responsibility that includes activities which draw on many departments, using different skills and levels of management expertise across the organization. Effective gluten management extends beyond technical departments and must involve commitment from research and development, production operations, engineering, distribution management, procurement, brand management, marketing, customer feedback, and human resource activity such as training.

The starting point for an effective GFMS is the commitment of senior leadership to the development of an all-encompassing policy to guide the activities that collectively assure food safety. The GFCP Global Standard places a high priority on clear evidence of senior leadership commitment.

An HACCP-based system

The program promotes the use of HACCP principles and a management systems approach, or the equivalent, to systematically prevent failures rather than to solely rely on end-product testing. Once in place, a product manufacturer conforming to the GFCP Global Standard will be subject to periodic audits by an independent third party approved by BRCGS. The audit will evaluate the

site's achievement, and any deficiencies, in the application and use of general best practices within its GFMS, with the expectation that conformity can consistently be met.

Types of product safety hazard controlled by a GFMS

The GFCP Global Standard uses product safety and HACCP principles to control physical, chemical, and biological hazards, with gluten control as a focus. The GFCP Global Standard addresses gluten as a chemical hazard and will certify sites that meet minimum good manufacturing practices and produce safe, gluten-free products. Most reputable manufacturers and distributors have prerequisite programs and other systems in place to prevent product safety failures from happening. BRCGS hopes not to duplicate what already exists but to allow industry partners to incrementally expand product safety programs to incorporate elements which, if correctly applied, will yield safe, gluten-free products that come from sites certified under the GFCP Global Standard.

Certification process

Producers and manufacturers will be evaluated and audited by a third party, a certification body recognized by BRCGS. The audit will evaluate the achievement, and any deficiencies, in the application and use of general best practices within the site's GFMS, with the expectation that conformity can consistently be met. Upon recognition, sites and their distributors will be licensed to use and apply the GFCP Global Standard trademark(s), knowing that products bearing the GFCP Global Standard trademark(s) must be sourced from a certified site in good standing.

Guidance and training

BRCGS produces a range of guidance documents, training courses, and a self-assessment tool designed to assist sites with the application of the GFCP Global Standard and provide an understanding of core skills such as risk assessment.

Further information about training courses can be found at **www.glutenfreecert.com**

Effective date

As with all revisions of the GFCP Global Standard, there must be recognition that a transition period is in place between publication and full implementation. This allows time for the retraining of all auditors and allows manufacturers to prepare for the new issue of the GFCP Global Standard. Therefore, certification against Issue 3 will commence from 1 August 2019. All certificates issued against audits carried out prior to this date will be against Version 2 and be valid for the period specified on the certificate of recognition.

Part II
Requirements

Part II
Requirements

All sites shall establish and maintain the environmental and operational programs (prerequisite programs) necessary to create an environment suitable to produce safe and legal food products. In addition, all sites shall conduct a complete hazard analysis, based on Codex HACCP principles, for all of their processes and products in order to identify and control all hazards effectively. Those sites that are not certified in a Global Food Safety Initiative (GFSI) benchmarked scheme must be certified in the BRC *START!* Program or an equivalent global markets program offered by a GFSI benchmarked standard owner.

1 Senior leadership commitment

CLAUSE	REQUIREMENTS
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.

CLAUSE	REQUIREMENTS
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 BRCGS.
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 remain the responsibility of the site.
1.6	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
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 • purchasing • transportation, receiving, shipping, and storage • equipment and maintenance • personnel and training • sanitation • pest control • traceability, recall, and withdrawal • 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 Gluten awareness training

CLAUSE	REQUIREMENTS
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 food 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
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.

3.3 Supplier approval, purchasing, and incoming ingredients and inputs

CLAUSE	REQUIREMENTS
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 which 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 BRCGS. 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 inputs must be current and shall be updated, at a minimum, when: • 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 • a new risk of gluten contamination emerges • there is a product recall or withdrawal in which a specific gluten-free ingredient or input is implicated.

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 BRCGS **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.
	
	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.

CLAUSE	REQUIREMENTS
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 amended). Only the correct version shall be released into production.

3.4 Approval and control of labels

CLAUSE	REQUIREMENTS
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 a label • physical comparison of received labels to approved labels • confirmation that externally printed labels meet the specifications agreed 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 created • updates whenever a change occurs that may affect the label information.

3.5 Marketing claims

CLAUSE	REQUIREMENTS
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 BRCGS • 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
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
3.7.1	Where applicable, and based on risk, the procedures and/or policies shall be developed and implemented to control substitutions and cross-contamination of undeclared gluten sources in the products. Such procedures shall include, as a minimum: • production scheduling if dedicated lines for gluten sources are not available • the traffic patterns of employees who handle gluten sources • the traffic flow and handling during the receiving, storage, processing, and packaging of ingredients containing gluten sources • dedicated uniforms and personal protective equipment for employees handling gluten sources • dedicated or segregated storage of ingredients containing gluten sources • the identification and sanitation of bulk containers housing a gluten source or ingredients containing gluten sources • dedicated utensils, equipment, and areas used to handle gluten sources • the handling and storage of rework product(s) containing ingredients that are gluten sources • the use of equipment, tools, and utensils with sound sanitary design • the cleaning of equipment/product contact surfaces/areas during operations if dedicated lines/equipment/areas for gluten sources are not available • dedicated maintenance and engineering tools • appropriate airflow • the control and separation of ingredients that are used in both gluten-free and gluten-containing production.

3.8 Work in progress

CLAUSE	REQUIREMENTS
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.

CLAUSE	REQUIREMENTS
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 waste material

CLAUSE	REQUIREMENTS
3.9.1	Where applicable, the procedures and/or policies for the segregation and safe disposal of obsolete materials shall be developed and implemented to prevent their inadvertent use (e.g., GFCP 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.

3.10 Laboratory and testing

CLAUSE	REQUIREMENTS
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 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
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 BRCGS 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 Recall

CLAUSE	REQUIREMENTS
3.12.1	The site shall notify the national, regulatory competent authority, certification body, and BRCGS of any recalls or withdrawals related to a gluten-free product. Notification to BRCGS 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
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)[3] • 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 verification procedures (HACCP Principle 6) • 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.

5 Records

CLAUSE	REQUIREMENTS
5.1	Records shall be kept to demonstrate the effective application of the control measure and to facilitate official verifications by the BRCGS 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.

3 Note: It is mandatory that gluten is identified as a hazard.

6 Document control

CLAUSE	REQUIREMENTS
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: • stored securely (e.g., authorized access, control of amendments, password protected) • backed up to prevent loss.

7 Validation

CLAUSE	REQUIREMENTS
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 site. 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, BRCGS recommends the Guidelines for the Validation of Food Safety Control Measures developed by the Codex Alimentarius Committee.

8 GFMS maintenance and reassessment

CLAUSE	REQUIREMENTS
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, such as 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 documented, and the validation recorded.

9 Internal audits

CLAUSE	REQUIREMENTS
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: • the GFMS, including the activities to implement the system (e.g., supplier approval, corrective actions, and verification) • prerequisite programs • procedures implemented to achieve the requirements of the GFCP Global Standard. 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.

Part III
Certification process and audit protocol

Part III
Certification process and audit protocol

This section details the process for the certification of sites and the licensing under the GFCP Global Standard. The program has been designed to accommodate any product from a site of any size.

Intuitively, a site exclusively dedicated to the manufacture and/or distribution of gluten-free products should have a less complex GFMS than sites where the influences of other ingredients or products containing gluten come into play. In the latter, the GFMS will need to incorporate virtual and/or physical barriers to ensure that the resulting products claimed to be gluten-free conform to the GFCP Global Standard requirements.

1 Application to BRCGS

All sites must complete the online application form prior to certification. This can be found on the GFCP website at www.glutenfreecert.com/product/gfcp-application

2 Program License Agreement

Upon review of the application, BRCGS will contact the applicant site to enter into a Program License Agreement (PLA). A separate agreement for fees, as determined by BRCGS, may apply according to the number of products that appear on Schedule A. Payment is due on an annual basis. The duration of the PLA can be one year or multi-year.

3 Schedule A

Sites must complete and submit a Schedule A and/or an equivalent approved BRCGS process. The Schedule A and/or agreed equivalent BRCGS process must capture all the gluten-free products that will be recognized under the GFCP Global Standard and may require updating from time to time.

4 Selection of an audit option

Audits must be arranged with the certification body for dates and times when gluten-free production is scheduled. The options and processes available for sites to demonstrate their commitment to the GFCP Global Standard are as follows:

- **Standalone audit** The focus of a standalone audit is only on the GFCP Global Standard requirements.
- **Combined audit** The focus of a combined audit is on the GFCP Global Standard requirements in conjunction with any other third-party food safety management system audit.
- **Unannounced combined audit** If there is no gluten-free production when the unannounced combined audit takes place, the audit may still be conducted providing the auditor can walk through the process and understand the controls that operate during gluten-free production. Records from previous gluten-free production runs shall be made available. In this case, the next GFCP Global Standard audit must be conducted while gluten-free production is taking place. This option (walk through) is not permitted if it is the first GFCP Global Standard audit.

5 Self-assessment of compliance

The GFCP Global Standard should be read and understood, and a preliminary self-assessment should be conducted by the site against the GFCP Global Standard, using the GFCP self-assessment checklist. Any areas of identified nonconformity should be addressed by the site before ordering an audit. This can be done as part of an internal audit.

Sites that are newly built or "commissioned" must ensure that systems and procedures in place are compliant with the GFCP Global Standard before an initial audit is undertaken. It is at the discretion of the site when they wish to invite a certification body to carry

Learn	• Visit the GFCP website • Contact BRCGS for more information
Apply	• Apply to the program • Receive the GFCP Global Standard and associated documents
Program License Agreement	• Enter into a Program License Agreement (PLA) outlining terms and conditions with BRCGS • Submit a Schedule A and/or equivalent approved process to BRCGS
Prepare for audit	• Select an audit option (standalone, combined, or unannounced combined) • Perform a self-assessment to determine compliance with the Standard • Select a certification body • Provide Information to certification body for audit preparation • Define audit date
On-site audit	• Opening meeting • Document review • Site inspection • Traceability challenge • Label review • Final review of findings by auditor • Closing meeting
Non-conformities and corrective actions	• Corrective actions provided for any non-conformities identified within 28 days • Certification body reviews evidence within 14 days • If corrective actions deemed satisfactory, certificate of recognition and audit report issued
Post audit	• Ongoing maintenance of the Standard and continual improvement • Use of GFCP trademarks • Ongoing communication with certification body • Schedule re-audit date before re-audit due date

out an audit; however, it is unlikely that full compliance can be satisfactorily demonstrated at an audit undertaken less than 3 months from commencement of operation.

6 Selection of a certification body

Audits against the GFCP Global Standard are only recognized if they are undertaken by approved certification bodies. A list of such bodies can be found on the GFCP website.

It is expected that a contract shall exist between the site and the certification body. The contract should contain clauses that allow the effective management of the GFCP Global Standard audit process.

The auditor(s) may be accompanied by other personnel for training, assessment, or calibration purposes. This activity may include:

- training of new auditors by the certification body
- routine certification body shadow audit programs
- witness audits by accreditation bodies
- witness audits by BRCGS.

7 Scope of audit

The audit shall include all applicable requirements within the GFCP Global Standard and all gluten-free production processes undertaken for the products listed on the site's Schedule A.

The product scope category of the audit shall be agreed between the site and the certification body in advance of the audit to ensure the allocation of auditor(s) with the correct product knowledge. The product scope category is determined by assessing the products produced and manufacturing processes, and it must align with one of the categories listed on the Food and Drug Product/ Scope Categories document in Appendix 2. At the time of the audit, the auditor will review the scope category listed on the site's Schedule A to ensure alignment.

8 Selection of auditors

It is the responsibility of the site to ensure that adequate and accurate information is given to the certification body, detailing the products it manufactures and the process technologies it uses, so as to enable the certification body to select an appropriate audit team with the required skills to undertake the audit.

The certification body and auditors must be aware of the need to avoid conflicts of interest when arranging for an auditor(s) to visit the site. The site may decline the services of a particular auditor offered by the certification body. Ideally, the same auditor is not permitted to undertake audits on more than three consecutive occasions at the same site.

Where the audit is not being carried out by the auditor(s) in the native language of the site, an appropriate translator, who has knowledge of the technical terms used during the audit, shall be provided. The final audit report must be submitted to BRCGS in English.

9 Duration of the audit

Before the audit takes place, the certification body shall indicate its approximate duration. The typical duration for a standalone is 1.5–2 consecutive days at the site. When a GFCP Global Standard audit is being combined with another food safety management audit, it will take at least an extra 0.5 days.

10 The on-site audit

A typical on-site audit consists of the following stages:

- **Opening meeting** To confirm the scope and process of the audit.
- **Document review** A review of the documented GFMS.
- **Production site inspection** To review the practical implementation of the systems, including observation of product changeover procedures and interviews with personnel.
- **Traceability challenge** Including a review of all relevant records of production (e.g., ingredients intake, production records, finished product checks, and specifications).

- **Label review** Including a review of a sample of gluten-free product labels to check against specification and legislation.
- **Final review of findings by the auditor(s)** Preparation for the closing meeting.
- **Closing meeting** To review audit findings with the site. A draft of the nonconformity report will be left with the site (note that nonconformities are subject to subsequent technical review by the certification body management).

The site shall fully assist the auditor(s) at all times. It is expected that, at the opening and closing meetings, those attending on behalf of the site will be members of the GFMS team.

The audit process gives emphasis to the practical implementation of the GFMS procedures and general good manufacturing practices. It is expected that the auditor will spend an appropriate amount of time auditing production, interviewing staff, observing processes, and reviewing documentation in production areas with the relevant staff.

During the audit, detailed notes shall be made regarding the site's conformities and nonconformities against the GFCP Global Standard, and these will be used as the basis for the audit report. The auditor(s) shall document all nonconformities and discuss them with the attending GFMS team representative at the time.

At the closing meeting, the auditor(s) shall present their findings and reconfirm all nonconformities that have been identified during the audit. Information on the process, and timescales for the site to provide evidence to the auditor(s) of the corrective action to close nonconformities, must be given. A draft summary of the nonconformities discussed at the closing meeting will be left with the GFMS team.

The decision to award certification will be determined independently by the certification body management, following a technical review of the audit report and the closing of nonconformities in the appropriate timeframe. The site will be informed of the certification decision following this review.

11 Handling nonconformities

Following identification of any nonconformities during the audit, the site must undertake corrective action to remedy the immediate issue(s) together with an analysis of the underlying cause of each nonconformity, which can then be used in preventive action. The action plan produced should include timelines and be provided to the certification body. Close-out of nonconformities can be achieved either by objective evidence being submitted to the auditor (either at the time of the audit or subsequent to it), which may include updated procedures, records, photographs or invoices for work undertaken, or by the auditor undertaking a further on-site visit, as appropriate.

If satisfactory evidence is not provided within the 28-calendar day period allowed for submission following the audit, certification will not be granted. The site may be required to have a further full audit in order to be considered for certification. No certificate shall be issued until the site can demonstrate that all nonconformities have been addressed. Nonconformities from the audit shall be checked during the next audit to verify effective close-out.

The certification body will conduct a technical review of both the evidence and any corrective action(s) being completed prior to awarding a certificate.

In some circumstances the number or severity of nonconformities raised at the audit prevents the site from being certified following that audit. This will be the case where a critical nonconformity is raised.

Nonconformities will be reviewed by the independent certification process of the certification body as soon as possible after the audit. Where the review confirms that a certificate cannot be awarded, the site will be required to undertake another full audit before an assessment for certification can take place.

Occasionally, the nature and number of nonconformities make it unlikely that they can be addressed, and fully effective improvements implemented and established, within a 28-day period. Therefore, the re-audit shall not take place any earlier than 28 days from the audit date.

Where this occurs at a certified site, the certification must be immediately withdrawn.

It is a requirement of some customers that they shall be informed when their suppliers have a critical nonconformity identified or fail to gain certification. In such circumstances the company shall immediately inform its customers and make them fully aware of the circumstances.

12 Audit reporting

Following each audit, a full written report shall be prepared in the agreed format. The final report shall be produced in English.

The audit report shall be provided to the site in a timely manner. The report shall accurately reflect the findings of the auditor during the audit. Reports shall be prepared and issued to the site within 42 calendar days from the first day of the audit, with a copy being sent to BRCGS.

The audit report and associated documentation including auditor's notes shall be stored safely and securely for a minimum period of 5 years by the certification body.

13 Certification

After a review of the audit report and documentary evidence provided in relation to the nonconformities identified, a certification decision shall be made by the designated technical reviewer. The certificate of recognition, if granted, shall be issued by the certification body within 42 calendar days from the first day of the audit. It shall include the required information found in Appendix 5. Trademarks owned or managed by BRCGS that are used on certificates of recognition shall comply with the GFCP brand standards.

While the certificate of recognition is issued to the site, it remains the property of the certification body, and that body controls its ownership, use, and display. The certification body shall inform BRCGS of its issuance and provide a copy.

All sites that achieve a certificate of recognition shall be entered into the list of certified sites.

All fees relating directly to the site must be paid in full to BRCGS prior to issuance of the certificate of recognition. Neither certification, nor the audit report, shall be valid until all fees have been received, irrespective of the outcome of the certification process.

14 Audit frequency and recertification

The frequency of announced audits shall be 12 months. The due date of the subsequent audit shall be calculated from the date of the initial audit.

The subsequent announced audit shall be scheduled to occur within a 28-day time period up to the next audit due date. This allows sufficient time for corrective action to take place in the event of any nonconformities being raised, without jeopardizing continued certification. Certificate expiry dates shall be calculated from the first day of the audit plus 75 days.

Where combined with a GFSI audit, the re-audit due date shall conform to the protocol of the relevant GFSI scheme.

15 Certificate expiry extensions

There will be some circumstances where the certificate of recognition cannot be renewed on the 12-month basis due to the inability of the certification body to conduct an audit. These justifiable circumstances can occur when the site is:

- situated in a specific country or an area within a specific country where there is government advice not to visit and there is no suitable local auditor
- within a statutory exclusion zone that could compromise food safety or animal welfare
- in an area that has suffered a natural or unnatural disaster, rendering the site unable to produce or the auditor unable to visit
- affected by conditions that prevent access to the site or restrict travel (e.g., inclement weather)
- producing seasonal products where production is delayed by a late start to the season (e.g., because of weather or product availability).

It is expected that the audit will be scheduled to ensure the availability of personnel and full production of gluten-free products. Deviations from this may be considered by BRCGS on a case-by-case basis.

16 Audits taken prior to due dates

In some circumstances it is possible to undertake the audit earlier than the due date; for example, to allow a combined audit with another food safety system audit. This is allowed on a case-by-case basis.

17 Suspension of a certified site

A site's certificate of recognition may be suspended if:

- the certified site does not comply with the requirements of the GFCP Global Standard or any other act or regulation that may impact on the gluten-free products being sold; or
- the operator fails to comply with the requirements of the GFCP Global Standard, the GFMS, or any other act or regulation that may impact on the gluten-free products being sold; or
- BRCGS and the certification body believe that public health will be endangered or the reputation of BRCGS, as well as the gluten-free status of products produced in the certified site, will be affected if the site is allowed to continue operating as a certified site; or
- the site is subject to a receivership or makes an assignment in bankruptcy.

If a certified site is in jeopardy of suspension, it will be notified of the existence of grounds for suspension and given evidence of any deviation from the requirements of the GFCP Global Standard. The certification body will specify corrective measures and dates for completion. If the site has failed or is unable to take corrective measures by the specified date, a notice of suspension will be delivered to the site.

The suspension of a site's certification shall remain in effect until the required corrective measures have been taken and verified as completed to the satisfaction of the certification body or BRCGS.

If an operator fails to pay any fee specified by BRCGS in accordance with the conditions of payment prescribed by it, the certification of a site to the GFCP Global Standard shall also be suspended until all outstanding fees are paid.

Note: BRCGS reserves the right to inform the brand owner (if different from the site) if certification is suspended. In the event of suspension of certification, the site must cease use of all associated logos and/or trademarks as per the site's PLA.

18 Withdrawal of certification

The certification body or BRCGS reserves the right to withdraw the certification of a site if:

- the site has not implemented the required corrective measures within an agreed timeframe; or
- the site has provided false or misleading information; or
- the site gives up certification by voluntarily withdrawing from the BRCGS GFCP.

Note: BRCGS reserves the right to inform the brand owner (if different from the site) if certification is withdrawn. In the event of withdrawal of certification, the site must cease use of all associated logos and/or trademarks as per the site's PLA.

Part IV
Management and governance

Part IV
Management and governance

Requirements for certification bodies

The GFCP Global Standard is a management system certification standard. In this standard, sites are certified upon completion of a satisfactory audit by an approved auditor employed by an independent third party – the certification body. The certification body in turn shall have been assessed and judged as competent by a national accreditation body, under ISO/IEC 17065 and/or ISO 17021-1, to perform food safety audits or specifically GFCP Global Standard audit services.

BRCGS recognizes that in certain circumstances, such as for new certification bodies wishing to commence auditing against the GFCP Global Standard, adding the GFCP Global Standard to their ISO 17065 and/or ISO 17021-1 scope may not yet have been achieved. This is because this accreditation process requires some audits to have been completed, which will then be reviewed as part of the accreditation audit of the certification body. The certification body must be able to conduct audits as part of the process of achieving accreditation, and so some unaccredited GFCP Global Standard audits under ISO 17065 and/or ISO 17021-1 will be performed. This will be permitted where the organization can demonstrate the following:

- current ISO/IEC 17065 or ISO 17021-1 accreditation for a GFSI or equivalent food safety scheme
- an active application, with an approved national accreditation body, to extend their ISO/IEC 17065 or ISO/IEC 17021-1 accreditation scope to include the GFCP Global Standard
- that accreditation for the GFCP Global Standard will be achieved within 24 months of the date of application and the experience and qualifications of the auditors are consistent with those specified by BRCGS
- a license is in place with BRCGS and all other license requirements have been met.

Governance and administration of the GFCP Global Standard

Achieving consistency – compliance

The maintenance of a high and consistent standard of audit and certification, as well as the ability of the certified sites to maintain the standards achieved at the audit, are essential to provide confidence in the scheme and enhance the value of certification. BRCGS therefore has an active compliance program to provide oversight of the work of accreditation bodies and ensure that high standards are maintained.

Sites may only be certified to the GFCP Global Standard by certification bodies licensed and approved by BRCGS and accredited by an accreditation body recognized by the same. All auditors undertaking audits against the GFCP Global Standard must meet the auditor competency requirements and be approved by BRCGS. The qualifications, training, and experience requirements for auditors who conduct audits against the GFCP Global Standard are comprehensive (see Appendix 1). All audits undertaken against the GFCP Global Standard shall be submitted to BRCGS.

BRCGS operates a compliance monitoring program that reviews the performance of the certification bodies, samples the quality of audit reports, assesses levels of understanding of the scheme requirements, and investigates any issues or complaints. As part of this program, feedback on its performance is provided to each certification body through a key performance indicator (KPI) program.

As part of the compliance program, BRCGS may audit the offices of certification bodies and accompany auditors on audits at sites to observe their performance.

Calibrating auditors

A key component of the GFCP Global Standard is the calibration of the auditors to ensure a consistent understanding and application of the requirements. All certification bodies are required to have processes to calibrate their own auditors. An essential element of this training and calibration is the witnessed audit program, which involves auditors being observed during an audit and provided with feedback on their performance. In order to ensure consistency between certification bodies, and for the purposes of accreditation, an audit may be witnessed by a representative from BRCGS or an accreditation body auditor. Guidelines apply to these activities to ensure that sites are not disadvantaged by the presence of two auditors. This process forms an essential part of the scheme and sites are obliged to permit witnessed audits as part of the conditions for certification. Auditors will be required to participate in training activities delivered through the certification body or BRCGS as part of their refresher training as and when required.

Feedback

Sites being audited against the GFCP Global Standard may wish to provide feedback to the certification body or BRCGS on the performance of the auditor. Such feedback, when and if sent to BRCGS, will be considered in confidence. Feedback provides a valuable input to the BRCGS monitoring program for certification body performance. All audited sites are invited to provide feedback to tellus@brcglobalstandards.com at any time.

Use of the trademarks

Certified sites that intend to use the GFCP owned or managed trademarks must meet all requirements outlined in the GFCP Trademark Usage Guide.

Sampling and testing

BRCGS may provide advice on testing methodologies and criteria for testing to verify and validate the efficacy of a GFMS, such as the list of official methods referred to in Appendix 5.

The site may be required to provide, at its own expense, laboratory proof of conformance with the GFCP Global Standard where there is reasonable suspicion of failure to meet the Standard's requirements.

Appendices

Appendix 1
Qualifications, training, and experience requirements for auditors

The certification body is responsible for ensuring that auditors acting for BRCGS meet, and can provide evidence of meeting, the following mandatory prerequisites and requirements:

- Provides an auditor profile and shows a proven track record for auditing food safety and quality management systems within the food or other industries as appropriate. This shall include:
  - a degree in food science, related major, or equivalent experience and training
  - 5+ years of experience in auditing food safety management systems within the industry
- Has completed a training course in HACCP (as evidenced by examination), based on the principles of Codex Alimentarius, of at least 2 days' duration, and is able to demonstrate competence in the understanding and application of HACCP principles. It is essential that the HACCP course is recognized by the industry (and its stakeholders) as being appropriate and relevant
- Has a recognized lead auditor certificate in good standing
- Participated and passed the GFCP Global Standard auditor training course and examination
- Participated in any refresher training and passed any associated examination as set and required under the GFCP Global Standard and achieved an auditor certificate approved by BRCGS
- Works under the authority of an approved BRCGS certification body.

The approved auditor will be involved in:

- assisting clients with questions relevant to the GFCP Global Standard audit and/or recognition process
- reviewing a site's gluten-free management system documentation and previous audit reports
- conducting on-site audits to verify and document evidence of conformity to the GFCP Global Standard
- writing comprehensive reports on the audit findings
- participating in opening and closing audit meetings and possibly conducting presentations of findings to the client
- providing clarification of any recommended corrective action requirements
- providing the approved certification body and administration team with audit reports, updates on status of work, nonconformance closures and any other projects as required
- assisting the administration team in addressing any appeals relative to the audit process or results
- where required by the certification body, completing technical reviewer tasks.

Ongoing requirements:

- refresher training once per year or as it becomes available
- retraining with each GFCP Global Standard revision
- completion of a minimum of 5 GFSI audits per year.

Appendix 2
GFCP Global Standard product/scope categories

Field of audit	Category no.	Category description	Product examples
Raw products of animal or vegetable origin that require cooking prior to consumption	1	Raw red meat	Beef/veal, pork, lamb, venison, offal, other meat
	2	Raw poultry	Chicken, turkey, duck, goose, quail, farmed and wild game Shell egg
	3	Raw prepared products (meat, poultry, fish, and vegetarian)	Bacon, comminuted meat and fish products (e.g., sausages, fish sticks), ready-to-cook meals, ready-prepared meat products, pizzas, vegetable prepared meals, steamer meals
	4	Raw fish products	Wet fish, mollusks, crustacea, comminuted fish, cold smoked fish
Fruit, vegetables, and nuts	5	Fruit, vegetables, and nuts	Fruit, vegetables, salads, herbs, nuts (unroasted)
	6	Prepared fruit, vegetables, and nuts	Prepared/semi-processed fruit, vegetables and salads including prepared ready-to-eat salads, coleslaws, frozen vegetables
Processed foods and liquids with pasteurization or UHT as heat treatment or similar technology	7	Dairy, liquid egg, pasteurized fruit juice	Liquid egg, liquid milk/drinks, cream, liquid tea and coffee creamers, yogurts, fermented milk-based products, fromage frais/crème fraîche, butter Ice cream Cheeses – hard, soft, mold-ripened, unpasteurized, processed cheese food Long-life milks, non-dairy products (e.g., soy milk), ambient yogurts, custards, etc. Fruit juices (includes freshly squeezed and pasteurized, smoothies) Dried whey powder, dried egg, dried milk/milk formulation
Processed foods, ready-to-eat or heat	8	Cooked meat/fish products	Cooked meats (e.g., ham, meat pâté, hot eating pies, cold eating pies), mollusks (ready to eat), crustaceans (ready to eat), fish pâté Hot smoked fish, poached salmon
	9	Raw cured and/or fermented meat and fish	Parma ham, ready-to-eat cold smoked fish, cured fish (e.g., gravlax), air-dried meats/salami, fermented meats, dried fish
	10	Ready meals and sandwiches, ready-to-eat desserts	Ready meals, sandwiches, soups, sauces, pasta, quiche, flans, meal accompaniments, cream cakes, trifles, assembled high-risk sweet desserts
Ambient stable products with pasteurization or sterilization as heat treatment	11	Low/high acid products in cans/glass	Canned or pouched products (e.g., beans, soups, meals, fruit, tuna); products packed in glass (e.g., sauces, jams, pickled vegetables) Pet food

Field of audit	Category no.	Category description	Product examples
Ambient stable products not involving sterilization as heat treatment	12	Beverages	Soft drinks including flavored water, isotonics, concentrates, squashes, cordials, minerals, table waters, ice, herbal drinks, food drinks
	13	Alcoholic drinks and fermented/brewed products	Beer, wine, spirits Vinegars Alcopops
	14	Bakery	Bread, pastry, cookies, cakes, tarts, breadcrumbs
	15	Dried products and ingredients	Soups, sauces, gravies, spices, stocks, herbs, seasonings, stuffings, pulses, legumes, rice, noodles, nut preparations, fruit preparations, dried pet food, vitamins, salt, additives, gelatin, glacé fruit, home baking, syrups, sugar, tea, instant coffee, and non-dairy coffee creamers
	16	Confectionery	Sugar confectionery, chocolate, gums and jellies, other candy
	17	Cereals and snacks	Oats, muesli, breakfast cereals, roasted nuts, crisps, poppadums
	18	Oils and fats	Cooking oils, margarine, shortening, spreads, suet, ghee Salad dressings, mayonnaise, vinaigrettes
Cosmetics	19	Applies to the manufacture, storage, and transport of cosmetics	Includes powder, lotion, lipstick, or other preparations
Pharma and natural health products	20	Applies to the manufacture, blending, transport, and storage of pharma and natural health products	Includes drugs and natural health products (not supplements; see #21)
Manufacture of dietary supplements	21	Applies to the manufacture, blending, transport, and storage of dietary supplements	Includes vitamins, minerals, probiotics, and supplements
Manufacture of packaging materials	22	Applies to the manufacture, storage, and transport of food sector packaging materials	All packaging materials, including flexible films, paperboard-based containers, metal containers, flexible pouches, glass containers, plastic and foam containers (PET, polystyrene, etc.)

Appendix 3
GFCP Global Standard certificate of recognition template

The certificate shall conform to the format shown below. Logos used on the certificate (e.g., GFCP, BRCGS, and accreditation body logos) shall comply with the respective rules of use.

While the certificate is issued to the company, it remains the property of the certification body, which controls its ownership, use, and display.

Auditor number(s)

CERTIFICATION BODY NAME OR LOGO

Certification body name (accredited certification body no.x) certifies that, having conducted an audit

For the GFCP product/scope categories

At the COMPANY NAME

AUDIT SITE ADDRESS

Meet the requirements set out in

Gluten-Free Certification Program Global Standard, Issue 3

Audit program: (e.g., standalone, combined, unannounced combined)

Date(s) of audit:

Certificate issue date:

Re-audit due date: from to

Certificate expiry date:

Authorized by

Accreditation body logo

BRCGS logo

Name and full address of certification body

Certificate traceability reference

This certificate remains the property of [name of certification body]

If you would like to feedback comments on the GFCP or the audit process directly to BRCGS, please contact TellUs@brcgs.com / +44 (0)20 3931 8150

To verify certificate validity, please visit www.brcdirectory.com

Appendix 4
Requirements for grain suppliers

Many grains are inherently gluten-free; however, because all grains are harvested, stored, and transported using the same equipment, gluten-free grains are often contaminated with gluten. Grain suppliers must conduct a risk assessment to determine if grain purchased from farmers can be effectively cleaned of wheat, barley, rye, or triticale to an acceptable level. Although grain cleaning, sorting, and sieving equipment can be very effective in removing gluten, on-farm controls may be necessary.

1 Purchasing

CLAUSE	REQUIREMENTS
1.1	Grain purchased from farmers as gluten-free product or intended to be processed as gluten-free shall not contain more wheat, barley, rye, triticale, or gluten-containing contamination than can be effectively removed using grain sorting and sieving equipment, as determined by a risk assessment and gluten-free process validation.
1.2	Grain that is purchased as gluten-free product shall be visually inspected upon receipt to ensure it can be effectively cleaned of gluten-containing grains to a level that meets customer and regulatory requirements as well as the needs of the GFMS plan.

2 On-farm controls

CLAUSE	REQUIREMENTS
2.1	The use of production contracts shall be controlled.
2.3	**Planting** The facility shall ensure that: • seed is sufficiently cleaned of foreign material to exclude viable gluten-containing grains (e.g., certified seed) • the previous land use and isolation requirements are defined to minimize the cross-contamination with wheat, rye, barley, and triticale or other gluten-containing grains • planters and seed drills are cleaned before planting a gluten-free crop.
2.4	**Cross-contamination** The facility shall ensure that: • cultivation practices have been defined and implemented to prevent cross-contamination • fields are inspected during the growing season and the presence of any foreign gluten-containing grain plants (as well as their removal) is recorded.

CLAUSE	REQUIREMENTS
2.5	**Harvesting** The facility shall ensure that: • processes have been defined and implemented to maintain product identity (i.e., purity) and to prevent gluten contamination during harvest • combine harvesters and trailers are clean and free from any seeds of other gluten-containing crops before harvesting • dedicated silos and storage bins are used for storing gluten-free product • handling equipment used to load and unload silos and storage bins are effectively cleaned after any gluten-containing grain has been in contact prior to use for gluten-free grains • harvested product is visually inspected for purity, and • if any of the harvested crop is found to be contaminated beyond the requirements of the facility, this part of the crop is not to be mixed with the rest of the harvested fields, and will be redirected to another market (e.g., feed).
2.6	**Transportation** Processes shall be defined and implemented to prevent cross-contamination of the crop during the transportation from the farm to the gluten-free grain handling facility. These include ensuring that: • the mode of transportation is thoroughly cleaned and free from other gluten-containing crops before being used for transportation • a process for the inspection and, if necessary, cleaning of the mode of transportation is defined and records of the inspections retained • where a third-party service provider is used to transport the harvest, a documented procedure for the inspection and, if necessary, cleaning of the mode of transportation is defined and records of the inspections retained.
2.7	**Discharge and storage at collection points** To prevent cross-contamination at collection points: • Purchased product shall be checked upon receipt to ensure that production requirements have been met by the grower. • On receipt, purchased product shall be sampled, visually inspected, and/or tested. The sample shall be kept for at least 6 months after the received grain lot has been shipped. • Where the use of dedicated gluten-free facilities is not possible, cleaning and flushing processes shall be in place and validated. • Processes shall be in place to ensure that gluten-free product is discharged into the correct gluten-free silos and out-loading is carried out from the correct gluten-free silo for each shipment.

CLAUSE	REQUIREMENTS
2.8	**Records** The facility shall maintain or have access to these process control records. Required records shall include the following, where applicable, and any other records deemed essential to ensure that process control has been implemented by the facility: • field maps • grower contracts • field history records • planting records • internal and external field inspection reports • harvest records • equipment clean-out records • stock seed tags • sampler declarations • testing records • storage records, bin records • shipping records and bills of lading

3 Prerequisite program considerations

CLAUSE	REQUIREMENTS

3.1	Design and implement a gluten control program by determining the cleaning, handling, and storage procedures and inspection standards that must be used to produce a finished product that meets the regulatory limits for gluten-free products. Validate the efficacy of the program.
	
	The potential risk of contamination by grains identified as a source of gluten is mitigated by ensuring that:
	
	• procedures are developed and validated to demonstrate their efficacy in reducing gluten-containing grains (wheat, barley, rye, and triticale) in the finished product to a level consistent with a maximum gluten level (e.g., 20 ppm or less) to meet customer demands. These procedures could include:
	  ◦ ensuring that all incoming grain is inspected and assessed by trained staff for gluten-containing grains
	  ◦ establishing limits on acceptable amounts of gluten-containing grain contamination for grain at receiving (e.g., 1 grain per 1 kg)
	  ◦ rejecting or redirecting grain that has more gluten-containing grains than can be effectively removed during processing
	  ◦ redirecting or reworking grain that has excessive gluten contamination if it has already been received into the facility
	  ◦ inspecting trucks, rail cars, and containers used for the transport of grain before and during loading to ensure they do not present a risk of cross-contamination with gluten-containing grains
	  ◦ verifying the gluten content of final product to ensure that it meets regulatory and customer requirements.
	• at receiving, the trucker hauling the grain is required to provide (or sign) an affidavit indicating previous load hauled and cleaning records to ensure that there is no potential cross-contamination with gluten-containing grain. Documentation should be obtained for all grain and inputs received from the trucker or grower, and compared against specifications for that delivery.
	• grain is received and handled using designated receiving pits, storage bins, and grain handling equipment. If this is not possible, documented procedures shall be established for cleaning and flushing equipment thoroughly in between commodities, and records of those activities shall be maintained.
	• training is provided on the processes and record keeping requirements, as outlined in the production contract, to contracted producers prior to seeding. Records of the training shall be retained.
	• contracted producers are evaluated on the quality of the preharvest or on-farm samples obtained, their past performance, and their compliance with contract requirements. Compliance can be assessed during reviews of the producer's on-farm records, visual evaluation and analysis of submitted samples, and through field inspections of gluten-free crops. The results of the review shall be recorded to evaluate producer compliance and eligibility for future gluten-free grain contracts.

4 Validation of gluten controls

CLAUSE	REQUIREMENTS
4.1	Validate the effectiveness of the gluten-control process by sampling grain and testing its gluten content using recognized analytical testing methodologies for the determination of gluten content in grain. This can be done as follows: • Determine the number of lots that will be sampled and obtain a representative sample of finished product for testing and validation. Samples should be taken from lots produced over a 3–6-week period of full production. The sampling should occur after all the cleaning steps but before the grain is packaged. • Test the sample for gluten using approved methodology for gluten assessment in grain. Retain the product on hold until the test is completed and results indicate that the product meets specifications. It is recommended that the internal threshold should not be more than 10–12 ppm gluten because of the currently approved testing methods that provide a 50–200% recovery of gluten in any given sample. • Develop corrective action procedures to handle product that exceeds the determined internal threshold (e.g., 10–12 ppm). Determine the disposition of the contaminated product (e.g., rework, redirect, or dispose) and conduct a root cause analysis to discover the source of contamination. This will probably result in a reexamination of the gluten control requirements, and a repeat of the validation process. • Document the procedures for sampling, testing, and taking corrective action. Keep and retain records of the results of these and any changes that have been made to the GFMS as a result of corrective actions taken.

Appendix 5
Guide to best practices for sampling and testing, and risk management for gluten

This sampling guide provides an overview of best practices for developing sampling plans and testing protocols to detect gluten in a wide variety of foods and on environmental surfaces. The approach is explained in five steps:

- Evaluate the risk of contamination
- Define the sampling parameters
- Determine the testing methodology
- Interpret the testing results
- Validate the program.

Figure 1 is a useful summary of this five-step approach. Each step (described in detail below) is accompanied by figures and tables to facilitate understanding of the important points.

This guide will aid sites in the development of a sampling plan based on risk assessment. The sampling program will detail how to test incoming materials, environmental surfaces, and finished products. It is important to note that, although testing is essential, finished products should never be deemed compliant based on gluten testing results alone, since a production's true gluten concentration can never be determined with 100% certainty. In addition, for some foods that are more likely to be contaminated, significant variability in sample analysis results is often noted.

1 Evaluate the risk of contamination

All manufacturers must evaluate the risk of contamination with gluten, for all incoming materials and for each processing step, before developing a sampling program. The objective is to ensure that the finished product meets regulatory requirements, or a lower limit imposed by the site.

1.1 Incoming ingredients and inputs

1.1.1 Supplier qualification

See requirement 3.3 of the GFCP Global Standard.

1.1.2 Conduct a risk assessment of incoming ingredients and inputs

Risk assessment can be conducted using several tools. For example, the scoring system presented in Schedule 1 can help manufacturers to classify incoming materials into three risk categories (i.e., low, medium, and high) by considering the ease of detection of gluten and the likelihood of occurrence.

1.1.2.1 *Ease of gluten detection*

Ease of gluten detection considers both the sampling and testing methodology's ability to accurately detect gluten in food samples. This measure can be influenced by some interfering food components and processing steps, and some products are more difficult to analyze than others, such as:

- food containing high amounts of polyphenols or tannins (e.g., tea, hops, cocoa products, coffee, spices, chestnut flour, buckwheat, millet)
- highly processed products (e.g., bread, pasta, baby food, snacks), and
- fermented and hydrolyzed foods (e.g., beer, soy sauce, sourdough, vinegar).

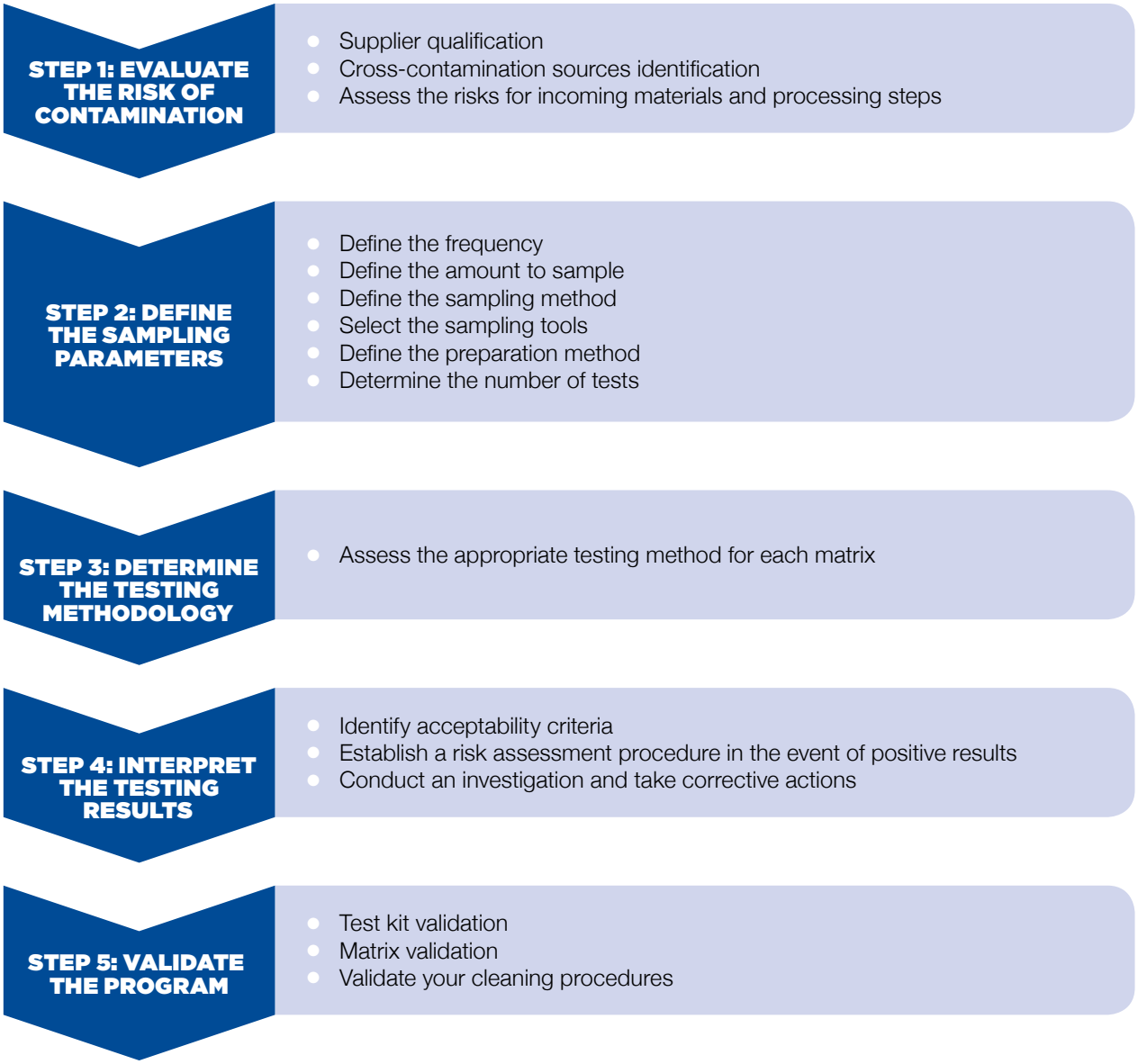

Figure 1 Five-step approach for developing a sampling plan

In the case of these food items, it may be necessary to use methods that are adapted to the specific challenges of these products (see section 3, this appendix, for more details). A sample's ease of detection may also vary according to its physical form, as gluten might not be homogenously distributed in all samples. Solid samples (e.g., bakery products, prepared meat) are usually more difficult to homogenize than liquids.

Gluten contamination in inherently gluten-free grains is usually extremely difficult to detect because it is generally not well distributed within samples. Indeed, when a sample is contaminated by a gluten-containing kernel, gluten-containing particles commonly coagulate into small masses during the milling process. This is called pilling of proteins in the scientific literature. Some particles may also stick to grinding equipment surfaces during sample preparation. These phenomena will contribute to a heterogeneous distribution of gluten in the sample and therefore to misleading analysis results.

Ease of access for sampling is another important factor to consider, since it influences collection of a representative sample. For example, sampling of large lots, such as bulk, can be difficult.

1.1.2.2 *Likelihood of occurrence*

The likelihood of occurrence is the probability that an ingredient contains gluten at a higher level than the regulatory limit (e.g., 20 ppm) or a limit that is self-imposed by the facility (e.g., 5 ppm or none detectable). Likelihood of occurrence mainly depends on the nature of the ingredient and the risk of cross-contamination by gluten-containing grains.

For example, grains, seeds, and legumes that are considered inherently free of gluten may still be at a high risk of cross-contamination by gluten-containing grains. The cross-contamination risk depends on the diversity and region of production. Separation techniques are used to clean the grains, but the effectiveness of these techniques depends on the physical properties of the grains (size, color, density, etc.). Ideally, products that are guaranteed or certified as gluten-free should be procured for an added level of assurance of lower risk.

Spices do not usually contain gluten, but on occasion they can be contaminated with gluten-containing grains or cross-contaminated during harvesting, transportation, or processing. Nevertheless, only very low quantities of spices tend to be added to product formulations (e.g., 1–2% by weight). It is important to distinguish spices from seasonings. Seasonings often comprise a blend of spices, herbs, salt, sugar, modified milk ingredients, starch flour, and/or an anti-caking agent. Since seasonings sometimes contain wheat flour, wheat starch, or hydrolyzed wheat protein, the risk is higher for such ingredients. It is therefore essential to carefully check the list of ingredients.

Schedule 2 explains the guidelines to assess the occurrence in several categories of products that contain or may contain gluten. This tool can be used to support a site's assessment in addition to the other information gathered when qualifying suppliers, such as the history of testing results and supplier control practices. For example, products that are certified as gluten-free by a third-party organization can be considered lower risk than products not certified. When buying products that are not certified or guaranteed to be gluten-free, the buyer carries full responsibility and accountability for the acceptance of high-risk products. This can be very costly without evidence of adequate upstream management by the seller.

1.2 Processing steps

1.2.1 Identification of cross-contamination sources

Potential cross-contamination risks should be evaluated at the site level. The extent of this work depends on the type of production and whether manufacturers process any gluten-containing products in the same facility. In a non-dedicated gluten-free facility, where both gluten-containing and gluten-free ingredients are present, assessment of risk factors should cover the entire processing operation. In a dedicated gluten-free facility, however, where no gluten enters the production or storage areas, some elements may not be applicable or necessary, as shown in Table 1.

Table 1 Some elements to cover in a risk assessment for the manufacturing of gluten-free products

Elements	Examples of cross-contamination with gluten	Non-dedicated gluten-free facility	Dedicated gluten-free facility
Receiving	Spillage during distribution and transportation	✓	✓
Storage	Spillage	✓	
Production	Air flow, shared equipment and utensils, improper production sequencing	✓	
Cleaning and sanitation	Cleaning tools, shared equipment, inadequate cleaning, poor equipment design	✓	
Maintenance	Maintenance tools, contractors	✓	✓
Personnel	Contamination by employees, visitors, contractors, and service providers (e.g., contaminated clothing or hands, job rotation practices)	✓	✓

1.2.2 Conduct a risk assessment for each processing step

Each processing step for which a cross-contamination risk exists must be assessed with an HACCP-based food safety system or equivalent. The hazard assessment must consider the likelihood of occurrence and severity as presented in the evaluation tool in Schedule 3.

Likelihood of occurrence is the probability that an undesirable outcome could occur, and in this case it depends on whether gluten is present in the same manufacturing environment. Measures of control in place (e.g., segregation, training, cleaning procedures, traffic patterns, air flow) should also be considered.

Severity measures the possible consequences of a hazard. For gluten, severity is highly influenced by the quantities involved if contamination occurs. For example, direct addition of wheat flour to a recipe represents a high risk, while cross-contamination from a wheat flour spill on to a packaging bag during transport is a lower risk.

2 Define the sampling parameters

The parameters of a sampling plan greatly depend on the outcome of the risk analysis. A good strategy is to test ingredients and products in their earliest, least complex forms and always within the context of a GFMS which focuses on a « start clean, stay clean » approach.

Incoming materials and processing steps that are at higher risk should be tested more intensively. Similarly, finished products manufactured in a site that produces both gluten-free and gluten-containing products should be tested regularly, especially if products are made on shared equipment or in a common room.

When designing sampling plans, many elements should be considered, such as the nature of the product, lot size, lot homogeneity, testing result history, and risk of cross-contamination. Sampling procedures generally consist of three essential steps: sample collection, sample preparation, and analysis. The effectiveness of each step can be maximized by making good choices when designing sampling plans (Table 2).

Table 2 Key elements to include in a sampling protocol

Steps	Key elements
Sample collection	Determine sampling frequency Determine quantities to be collected to obtain a representative sample (number of samples, time interval, sample size) Choose the right sampling tool
Sample preparation	Assess uniformity of subsamples Determine the preparation method to homogenize samples Clean equipment
Analysis	Choose the proper testing method according to the sample type Determine the number of analytical measurements

2.1 Sample collection

It is important to ensure that samples are randomly collected from a lot in a manner that gives each sample an equal chance of being chosen. Selecting a representative sample is critical, since only a very small amount of the sample is usually analyzed.

Commodities contained in bins, boxes, bags, totes, trucks, rail cars, or other static containers should be sampled from different locations randomly dispersed throughout the lot. The number of samples per container and the sample size should be based on the lot size and risk assessment to ensure a good representation of the entire lot.

When samples are collected in dynamic lots where the product is moving (e.g., when unloading bulk grains), small quantities should be collected at frequent and uniform intervals at a specific sampling point. Samples can then be combined to form a composite.

When sampling, it is also important to use appropriate sampling devices depending on the type of product sampled, the type of container, and the sampling method. For example, sampling spears (Figure 2) can be used to sample grains in static containers. Sampling spears are available in different lengths, and should be selected according to crop type.

It is also possible to use manual tools such as hand scoops, buckets, or automatic sampling devices, more specifically when the product is sampled from a dynamic lot. Conversely, when the product is transferred in a completely closed circuit, it is important to designate a place where an adequate sample can be collected.

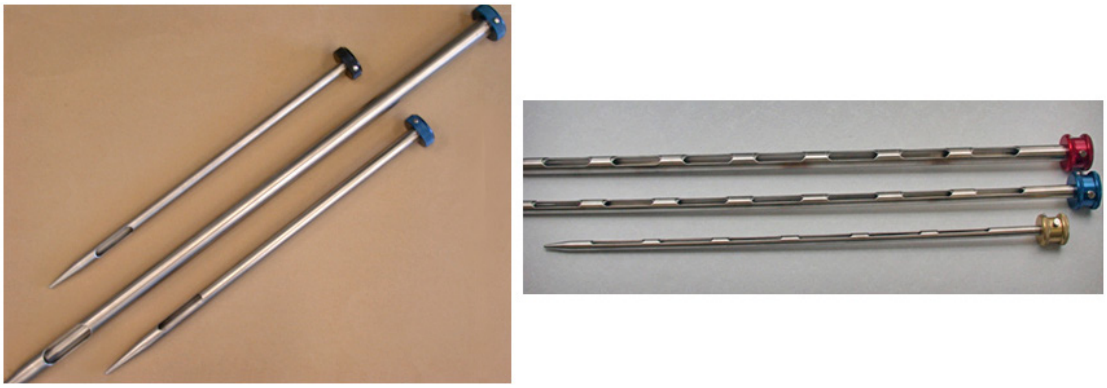

Figure 2 Different sizes and types of sampling spears

Incoming materials should be visually inspected upon their arrival at the plant and/or analyzed using a rapid gluten test kit. Testing frequency should be determined according to the risk assessment results, since it might not be necessary to test all incoming materials at each delivery. Risk level, lot size, and frequency of delivery must also be considered. Table 3 provides an example of testing frequencies for incoming materials.

Table 3 Example of determination of testing frequency of incoming materials

Risk level	Minimum testing frequency
Low	Once a year
Medium	Every 2 to 5 receiving lots
High	At each delivery

The sample size and the number of samples to collect depend on the homogeneity of the product from which the sample is drawn. To do this, it is important to consider the statistical validation. For example, for incoming materials, five subsamples of a minimum of 100 grams from different locations throughout the same lot should be collected, ground to a suitable sieve size, and combined to reduce variability (see Canadian Grain Commission in References). However, smaller amounts could be collected for ingredients received in very small quantities (e.g., spices).

Sampling of incoming materials and testing must be conducted as quickly as possible after ingredients are received. Ideally, incoming materials should not be unloaded in the site's facilities until testing results are available to avoid introducing a source of gluten; this is particularly important for bulk ingredients unloaded directly in storage facilities (e.g. silo, tank).

The development of sampling plans to determine gluten concentration of finished products is complex, and there is currently no standardized sampling method that is acceptable for all types of food. Testing frequency of finished products should also be determined based on the risk assessment results. Analyzing all finished products at least once a year is recommended, but may be more frequent; for example, each lot of products considered high risk should be tested.

Finished product testing is the final step in verifying a gluten control program. Although testing is essential, finished products should never be deemed compliant based on gluten testing results alone, since a production's true gluten concentration can never be determined with 100% certainty. In addition, for some foods that are more likely to be contaminated, significant variability in sample analysis results is often noted. Thus it is best to use different approaches to check the absence of gluten in your product throughout its processing. For example:

- Check the cleanliness of direct food contact surfaces with swabs once the production line has been cleaned or after maintenance. Target shared equipment, areas known to be difficult to clean, and dead spots.
- Check the first products coming off the production line after changeovers. When wet cleaning is impossible or restricted (e.g., flour, chocolate), be sure to check the purge product at reasonable intervals after leaving the production line. The product can be considered safe when two consecutive samples (e.g., after 3 and 5 minutes) meet the limits established in your cleaning validation procedure.

- Check the gluten concentration of rinse water after the cleaning cycle when a cleaning-in-place system (CIP) is used. Some gluten lateral flow devices (LFDs) are specifically designed for this type of analysis. Note: CIP is a validated test matrix.
- Check the packaging of incoming materials visually and using gluten test kits.
- Check for gluten on employees' hands and clothing with a swab and analyze using a gluten test kit.
- Swab both the production environment and the ventilation grids, and analyze using a gluten test kit to confirm the absence of gluten, especially when using volatile ingredients (e.g., flour).
- Collect and analyze air samples using an air sampler.
- Check tools used when servicing equipment, especially of subcontractors.

When collecting in-process samples, taking samples of 100 g to 1 kg throughout the production run is recommended, depending on the sample type. In some cases, and according to risk, subsamples may be combined to form a composite sample. Composite sampling can help companies reduce costs and increase the probability of finding gluten. However, it may also dilute low amounts of gluten to an undetectable level. For this reason, composite samples should not be used for products that are difficult to homogenize. Individually analyzing multiple units of these products is highly recommended.

It is essential that sites implement rigorous sampling protocols; thus the people performing the sampling should always wash their hands and sampling equipment. Furthermore, before collecting a sample using a probe or spear, the packaging exterior must be cleaned to avoid contaminating the sample. The holes must then be securely sealed with a label or adhesive tape and, lastly, each lot analyzed must be placed in quarantine until the results are obtained and meet specifications. Subsamples must be kept in a secure place, so they can be retested as needed.

2.2 Sample preparation

Samplers should assess the uniformity of each subsample by verifying its color, size, shape, and the presence of visible impurities before adding it to a composite sample. Composite samples should be mixed thoroughly to make them as homogenous as possible.

Different techniques can be used depending on the type of sample and the sample size. Granular and solid samples are usually reduced to powder with a coffee grinder, mill, or food processor. The equipment should reduce particles in the test sample to the smallest size possible. The sample should then be measured (e.g., sieve size) and recorded. This will increase the homogeneity of the test sample and reduce variability. Gluten contaminants are known to be difficult to disperse within a ground sample due to kernel hardness and pilling of proteins, resulting in highly concentrated pockets of gluten even after grinding.

Liquids, pastes, and fine powders are usually more homogenous and can be blended with a food processor or mixed manually.

Equipment used to prepare samples should be cleaned between each sample to avoid contamination and preserve the integrity of the next sample. Rinsing equipment with an ethanol solution is highly recommended, as gluten is soluble in ethanol but not in water.

2.3 Analysis

The gluten content of a sample can be detected or quantified using various analytical procedures. Selecting the right testing methodology is essential and depends on many factors. Details in section 3 (this appendix) give guidance on how to choose an appropriate method.

Typically, a very small portion of the sample is withdrawn for analysis. For example, rapid gluten tests are conducted on a sample of 0.25–1 g. It is important to follow the instructions of the test manufacturer. Some manufacturers suggest modified testing protocols to users to allow for the testing of a larger sample (see the case of oats in Schedule 4). Analyzing a larger sample size improves confidence in testing results but may make testing significantly more expensive.

Analytical errors and the variability of the testing results can also be reduced by increasing the number of measurements for the same subsample. Duplicates or triplicates are usually recommended, especially for high-risk products.

To avoid contamination during testing, performing the analysis outside production rooms and wearing gloves during the assay is recommended. Materials should be cleaned and stored properly. Personnel should also be trained to ensure compliance with good manufacturing practices. Split samples should also be stored for use at a later date, if needed for comparison.

Table 4 Main characteristics of ELISA and LFD analysis methods

Elements	Quantitative method		Qualitative method
	Sandwich	**Competitive**	**Lateral flow devices (LFDs)**
Time to get results	45 minutes–3.5 hours	1 hour	5–15 minutes
Expertise	Requires laboratory equipment and trained personnel Mostly conducted in external laboratories	Requires laboratory equipment and trained personnel Mostly conducted in external laboratories	Easy to use, tests can be conducted internally with little equipment Results are sometimes difficult to read
Sensitivity	Generally very sensitive (⩽5 ppm)	Depends on the food matrix to evaluate, generally ⩽10 ppm	Less sensitive, varies according to the test kit (⩽5–20 ppm)
Cost	More expensive	More expensive	Less expensive
Application	Generally used for finished products and ingredients Can be used for surfaces, but qualitative results only Not appropriate for assessing fermented and hydrolyzed products	Raw/unheated products Fermented and/or hydrolyzed products	Fast screening of ingredients, in-process samples, surfaces, and rinse water Finished products can be analyzed, but validation is needed Most kits are already validated by kit manufacturer, but each matrix should be validated

3 Determine the testing methodology

There is currently no general agreement on a single "best" analytical method that should be used to measure the gluten content of all food products. The choice of testing method depends on the product, also taking into consideration the fact that each testing method has its own strengths and weaknesses. See Table 4 for a comparison of ELISA and LFD.

3.1 General overview of testing methods available

There are a variety of testing methodologies available to either run either on site or at a commercial laboratory. The four commonly available testing methodologies are: lateral flow device (LFD; also known as lateral flow immunochromatographic assay), enzyme-linked immunosorbent assay (ELISA), polymerase chain reaction (PCR), and mass spectrometry (MS, or liquid chromatography–mass spectrometry LC-MS). These methodologies differ in their cost, time, precision, and information gained.

LFD and ELISA methods are based on antibodies raised against specific amino acid protein sequences, and the reactions are made visible by color development. These two technologies comprise the majority of gluten analyses conducted.

LFD is currently offered as a qualitative (screening) method and is the most common technology used on site, owing to its speed, cost, and ease of use. Many options are commercially available, differing in antibody reactions, limits of detection, validated usage, and assay time. Schedule 5 offers more detailed information about these test kits.

ELISA test kits are the main methods of quantification and are used by most commercial laboratories and compliance agencies. There are two types of ELISA methods: sandwich and competitive. Sandwich ELISA methods work well for both raw/unprocessed and heated/processed samples (with use of method-specific extraction cocktail). Competitive ELISA methods were developed to analyze allergenic protein fragments that are not intact enough for accurate results using sandwich ELISA. This fragmentation is most commonly caused by fermentation or hydrolysis of the gluten protein. ELISA methods are typically more expensive and more labor-intensive than LFDs. Schedule 5 offers more detailed information about these test kits.

PCR and LC-MS methods are almost exclusively conducted at commercial laboratories and are treated as confirmation methods. PCR detects DNA, which can be helpful with confirmation of difficult matrices; however, it is difficult to correlate DNA to ppm

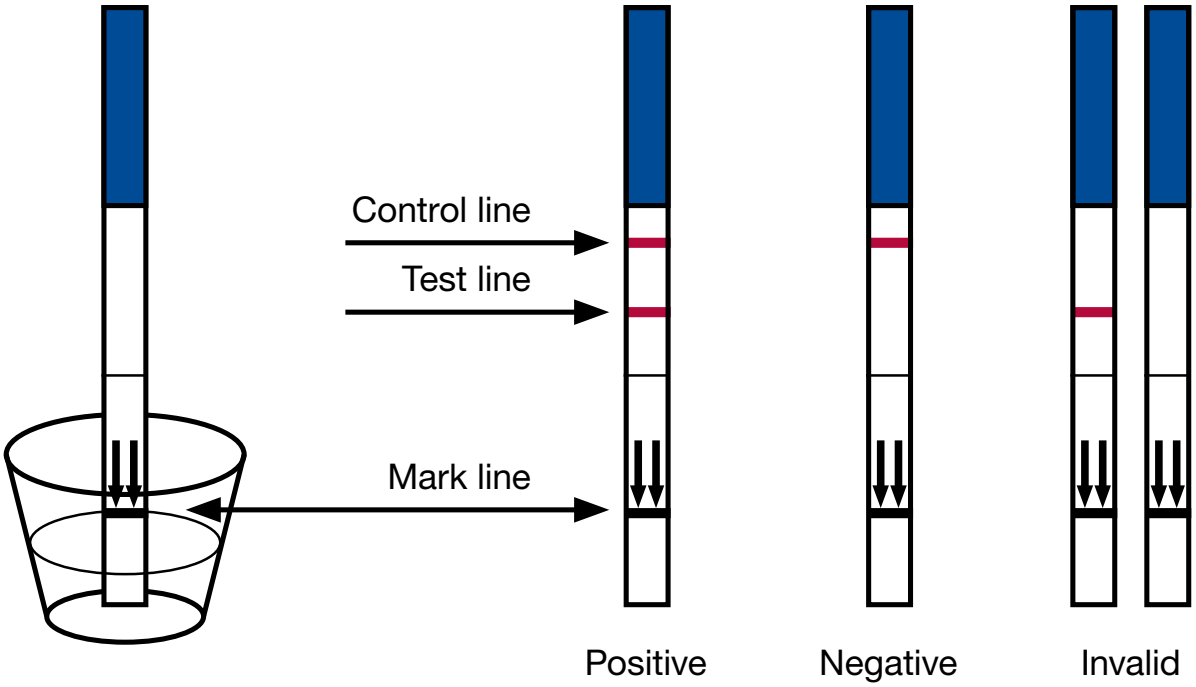

Figure 3 Example of an analysis with a gluten LFD

protein contamination. LC-MS technology is a very high-level analysis and detects peptides (protein fragments). It is currently difficult to calculate the sample total gluten ppm value with LC-MS, and the analysis is relatively costly.

When using a gluten LFD, a small quantity of the sample is extracted. A test strip is then inserted into the solution. The strip absorbs the gluten extraction solution, allowing the antibodies to bind with the sample if gluten is present. The antibodies and the sample migrate together across the surface of the strip and the reaction becomes visible, as illustrated in Figure 3. The sample is considered to be positive if two colored lines are visible and negative if only the control line is visible. Moreover, in all cases, if the control line is not visible the result is invalid, and the test needs to be repeated. The intensity of the colored test lines may vary, making it difficult to read the results. Some LFDs may be subject to the hook effect, resulting in a false negative result. Consult the test kit manufacturer for details.

When choosing a testing methodology, it is important to consider:

- time needed to obtain the results
- expertise required
- cost
- the matrix (e.g., state of food, formulation) and sample preparation
- expected results (quantitative, qualitative, identification of gluten sources)
- sensitivity and performance (limit of detection, limit of quantification, and other technical specifications).

3.2 Assess appropriate testing methodology

Companies should select the most appropriate testing method, which will depend on the type of food they are analyzing and the type of contamination possible. Several ELISA and LFD test kits are available on the market. Schedule 5 presents the main characteristics of the tests most used by the industry. Unfortunately, none of them are considered universally acceptable for all food matrices.

Gluten test kits often give different results when compared to each other, because different antibodies (R5, G12, Skerritt, etc.) target different peptides, and different standards are used to calibrate the assays. Extraction protocols may differ as well. Gluten is insoluble in water, so ethanol is widely used to extract it from food. Cocktail solutions have been developed and should be used by food product manufacturers to improve the extraction of gluten in samples.

Table 5 Guidelines for determining the appropriate method of analysis

Product	Potential problems	Recommended method of analysis
Heated and extruded products	The protein structure is modified, which makes proteins difficult to extract with ethanol	Use cocktail extraction with a quantitative ELISA test kit or gluten LFD
Foods containing polyphenols and tannins	Gluten content is overestimated due to polyphenol and tannin interactions with proteins	Test with a quantitative ELISA method or gluten LFD. Extraction additives may be necessary. See test kit protocols
Extreme conditions (e.g., strong acid/alkali, high salt, high fat) or presence of food gum	Various interactions are possible, influencing gluten extraction	Test with a quantitative ELISA method (external laboratory) or gluten LFD
Hydrolyzed or fermented products	Gluten content is underestimated with sandwich methods, since proteins are broken down into smaller fragments	Opt for a competitive ELISA method
Food containing both intact and hydrolyzed/fermented proteins	Gluten content is underestimated in the presence of both types of proteins	Use both sandwich and competitive ELISA methods
Distilled products	The removal of gluten depends on the effectiveness of the distillation process Most products are fermented	Verify the effectiveness of distillation for finished products by either measuring the total protein content or using a competitive ELISA method For ingredients, choose a competitive ELISA method if the product has been fermented, in combination with a sandwich method
Enzymes	Contamination by fermented proteins and false positives are possible	Opt for a competitive ELISA method, and consult test kit manufacturer for specific procedural requirements
Packaging materials (food contact)	Surfaces should be swabbed	Choose a compatible gluten test kit for swabbing
Surfaces and production environment	Surfaces should be swabbed	Choose a compatible gluten test kit for swabbing
Inherently gluten-free grains, seeds, and legumes	Very heterogeneous matrices	Visual inspection before performing any processing steps may be valuable. Test with a quantitative ELISA method or LFD with a limit of detection of ⩽5 ppm. Take special care when grinding prior to testing
Gluten-free oats	Certain oat varieties are detected by the G12 antibody, resulting in false positive results. The Skerritt antibody has a weak response to barley	Visual inspection of ingredients before performing any processing steps may be valuable. Use an ELISA test kit based on the R5 antibody with a limit of detection of ⩽5 ppm. Take special care when grinding prior to testing

It is important to understand that some test kits and extraction protocols work very well with some matrices but not with others. Special attention should thus be given to the products presented in this section to choose the optimal testing methodology (Table 5).

3.2.1 Heated and extruded products

When proteins are heated, baked, or extruded, their structure is modified, and gluten proteins aggregate under these conditions. These changes result in a lower detectability of proteins in ethanol, which is the main solution used to extract gluten. Cocktail solution developed by test kit manufacturers should be used rather than ethanol to improve recovery of gluten for samples that have been heated or extruded.

Assessing the gluten content of finished products with a quantitative sandwich ELISA test that has been fully validated with the proper matrix is highly recommended. LFDs may also be used if matrices are validated, as explained in section 5 (this appendix).

3.2.2 Foods containing polyphenols and tannins

When foods contain large amounts of polyphenols or tannins (e.g., tea, hops, cocoa products, coffee, spices, chestnut flour, buckwheat, millet), detecting and quantifying gluten is more difficult. These constituents create interactions with proteins that affect the detection and quantification of gluten. The accuracy of test results can therefore be reduced. Overestimation of the gluten content can be avoided by adding extraction additives such as fish gelatin, skim milk powder, polyvinylpyrrolidone (PVP), or urea to the extraction solution. These additives disrupt gluten protein–polyphenol interactions, thereby rendering the gluten result more accurate.

The gluten content of these types of foods can be assessed with a quantitative ELISA test method or with rapid LFD. Special instructions provided by the test kit manufacturer should be followed. The method should always be validated for foods containing high amounts of tannins and polyphenols (see section 5, this appendix). Test kit manufacturers can assist you in developing special extraction protocols when problems are encountered.

3.2.3 Extreme conditions (strong acid/alkali, high salt, etc.)

Foods are complex matrices made of various components, and the interaction between ingredients can have an impact on gluten detection. Gluten test kit performance might also be affected in extreme conditions, such as the presence of strong acid or alkali, or high amounts of salt, fat, sugar, food gums, food additives, artificial coloring, or flavors.

Many of these extremes are controlled by buffer solutions during the extraction process. However, the gluten recovery rate should be validated for each matrix.

3.2.4 Hydrolyzed and fermented products

During fermentation and hydrolyzation, gluten proteins are broken into smaller fragments, which make them difficult to detect. Hydrolyzed and fermented peptides are found in many manufactured products, such as beer, distilled alcohol, hydrolyzed proteins, vinegar, malt extract, sourdough, soy sauce, glucose syrup, guar gum, xanthan gum, and starter cultures.

Sandwich ELISA-based test methods are not appropriate for assessing the gluten content of these kinds of foods because proteins are broken down into smaller fragments to such an extent that gluten proteins become too small, or are chemically altered, so that the two antibodies are unable to attach to different binding sites. In these circumstances, only the competitive method is suitable, as only one binding site is necessary for detection.

It is also important to consider that foods may contain proteins with different types and degrees of hydrolyzation and/or fermentation (e.g., wheat starch, wheat starch hydrolysates, brewer's yeast, yeast extract). Food containing both intact and hydrolyzed proteins, and food that could be contaminated after fermentation or hydrolyzation, should be analyzed using both sandwich and competitive tests. This applies also to food that could be contaminated after fermentation or hydrolyzation.

3.2.5 Distilled products

During distillation, where a liquid is heated, volatile components such as alcohol and flavors are separated from non-volatile materials such as proteins and sugars. Generally, distilling alcohols and vinegars eliminates residual proteins and is thus considered a process for removing gluten, resulting in an inherently gluten-free product. However, the effectiveness of the distillation process can have an impact on the purity of the final product. It is also important to know that not all vinegars are processed by distillation (e.g., malt vinegar). In addition, cross-contamination could occur during or after processing, especially in a gluten-rich environment.

As the production of vinegars begins with the fermentation of grains or fruits into alcohol that is further fermented by acetic acid bacteria, products should be analyzed by a competitive ELISA assay in combination with a sandwich test.

3.2.6 Enzymes

Some enzymes have been shown to react with ELISA assays, causing alarmingly inconsistent results. When enzymes are tested for gluten, they should be deactivated first to prevent false results.

As enzymes used by the food and dietary supplement industry are typically produced on a wheat fermentation media, they should be tested with competitive ELISA methods. External laboratories should develop an appropriate testing protocol in collaboration with their test kit manufacturer.

3.2.7 Packaging materials (direct contact)

Most packaging materials are naturally free of gluten. However, in rare cases, packaging materials and wax paper may be coated with gluten-containing materials. For example, gluten can be found in some cardboard box adhesives. Wheat gluten can also be used as an additive in plastic formulations to enhance mechanical performance, especially for renewable and biodegradable products. A risk of cross-contamination also exists, since many packaging companies also handle products that contain gluten.

The gluten-free status of packaging materials cannot be verified in the same way as other ingredients. However, it is possible to directly swab your packaging material and analyze using a gluten test kit, as with environmental surfaces. It is important to swab the areas that are the most likely to be contaminated (e.g., contact surfaces, joints and corners of boxes, wax coatings).

3.2.8 Surfaces and production environment

The absence of gluten on surfaces and in the production environment should be checked using LFD or a quantitative ELISA method. LFD is a specific method that has the advantage of giving results in just a few minutes, which makes it possible to act quickly in the event they are positive.

3.2.9 Inherently gluten-free whole grains, seeds, and legumes

A visual inspection should be carried out on a representative sample of cereals, seeds, and legumes prior to unloading, owing to the heterogeneous nature of these products. To do this, take several subsamples of about 500 g to 1 kg, depending on the size of the batch that will form a composite, and visually inspect the sample on a white surface to find other cereals that contain gluten. Note, this inspection should be done by a person trained to recognize the different types of cereals and seeds.

The gluten-free status of grains, seeds, and legumes can also be confirmed by testing the product with a gluten test kit that has a detection limit of ⩽5 ppm. Special care should be taken when preparing the samples to ensure their homogeneity.

3.2.10 Gluten-free oats

Oats are recognized as being structurally different from other gluten-containing cereals, making oat proteins generally undetectable by gluten test kits. The majority of clinical studies have shown that most people affected by celiac disease can consume oats without any adverse effect on their health if the oats are not contaminated with wheat, rye, or barley. However, oats pose a high risk of contamination with gluten in the absence of special on-farm, transport, storage, handling, and cleaning procedures. Moreover, gluten is often unevenly distributed in products, making oats difficult to sample and test.

The gluten-free status of oats should always be confirmed with a fully validated test kit based on the R5 antibody with a limit of detection of ⩽5 ppm. Certain oat varieties can be detected by the G12 antibody, which can result in false positives. The Skerritt antibody was found to give a weak response to barley, one of the principal contaminants of oats. As with other grains, special care should be taken when preparing the samples to ensure sample homogeneity.

4 Interpret the testing results

Regulations provide a standard for manufacturers across the food industry, and adherence to these standards helps consumers to be confident that products labeled as gluten-free are safe. The GFCP Global Standard mandates a threshold of less than 20 ppm or lower, depending on regulatory limits of the country of destination.

When analyzing gluten-free products, testing results should be interpreted with care. Gluten concentration should be compared to the regulatory limits of the country of destination in order to determine the product's safeness. Figure 4 illustrates a recommended method for determining the acceptability of a lot based on testing results for a product sold in Canada or the USA and analyzed with a quantitative gluten test kit.

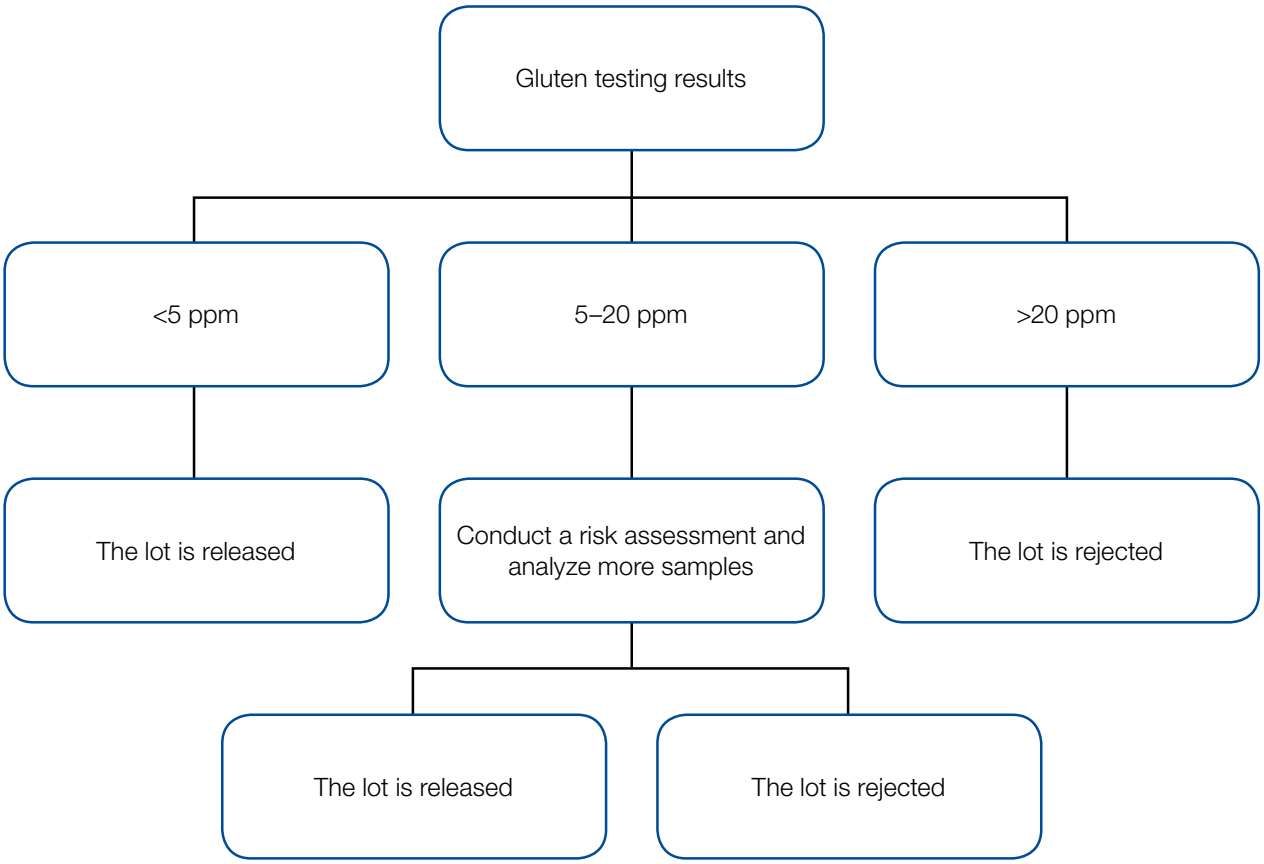

Figure 4 Example of a decision tree for determining lot acceptability according to testing results

It is important to understand that a negative result (i.e., none detected) does not necessarily indicate the absence of gluten in a lot, as gluten may not be homogenously distributed, or the level of gluten in the product might be below the limit of detection. Acceptance of the lot after a result of less than 5 ppm greatly depends on the effectiveness of your sampling plan.

When positive yet compliant results are obtained (typically between 5 and 20 ppm), particularly in the case of a first reading, a risk assessment should be performed to determine if the lot can be accepted. Testing more samples is generally recommended, since higher levels of gluten could be found in other samples from the same lot. The number of subsamples to retest depends on the type of product tested and its homogeneity. Retesting a minimum of 5 to 10 additional samples is generally recommended. If composites are tested, each of the subsamples should be retested at least once. When interpreting results, consideration should be given to the type of product tested, the source of contamination, and the homogeneity of the analytical results. It is important not only to consider the risk for gluten at a level of 20 ppm but also for allergens (e.g., wheat) that are known to cause severe adverse reactions, even in small doses.

Finally, testing results greater than 20 ppm of gluten should always lead to the rejection of the lot. Appropriate corrective actions should be taken and documented. For example, ingredients could be returned to the supplier, following which a re-evaluation of the risk category and the number of samples to analyze should be conducted. For finished products, the batch should be destroyed, sold as a non-food (e.g., animal feed), or directed to the food supply with appropriate labeling.

5 Validate the program

5.1 Test kit validation

Test kit manufacturers should conduct a premarket validation study. Most test kit manufacturers publish the results of their validation on their websites. Furthermore, some test kits have achieved international validation through a recognized third-party organization (e.g., AOAC, CODEX, AACCI, ASBC). It is important to keep in mind that validation studies are usually conducted under optimal conditions and for a limited number of food matrices.

External laboratories should also validate manufacturers' methods. Before sending your samples to an external laboratory, you should verify if the laboratory has obtained ISO 17025 accreditation from a competent authority (e.g., ANAB, Standards Council of Canada). You should also verify that the laboratory's methods fall within the scope of its accreditation, and that the methods have been fully validated at its site for your matrix.

Testing validation involves adding a known amount of gluten to a sample (i.e., spiking) in order to attempt to recover the same quantity. Ideally, a recovery of between 80% and 120% should be achieved. However, a recovery of 50% to 150% is usually considered acceptable for allergens, including gluten, as long as the results can be shown to be consistent.

5.2 Matrix validation

Before using an LFD, you are strongly recommended to conduct an internal validation of each type of food matrix. Indeed, some matrices may not be suitable for certain types of analysis, thus causing false positives or false negatives. Validation demonstrates the compatibility of a matrix with the analytical method, verifies the ability of the analytical method to detect known amounts of gluten, and avoids misinterpretation of the analytical results.

It is important to validate the effects of the matrix you want to analyze to account for possible interference. For example, high levels of tannins, polyphenols, fat, sugar, salt, gelling agent, or acidity may interact with the proteins and mask the presence of gluten in the sample. Other constituents could cause false positives because of their very similar structure to gluten.

Each food matrix that you analyze should be validated. If it is not possible to validate all your matrices, the risk assessment will allow you to target the complex ones. Validation results published by test kit manufacturers can help you choose products for which validations are required.

5.2.1 Validation procedure for gluten LFDs

5.2.1.1 *Prepare spiking material*

Spiking material may be prepared by the site, or a commercial standard may be used. The spiking material should mimic sample contamination. It is therefore important to understand what type of proteins could contaminate the sample. In most cases, non-processed wheat gliadin is used. However, in specific cases, it could be appropriate to use processed proteins, barley hordeins, or another mixture.

To prepare the reference material in-house, add a known amount of wheat flour into a gluten-free flour (e.g., rice flour) and validate the concentration of the mixture with a quantitative analysis by using an external laboratory. The accuracy of the result will depend on the homogeneity of the spiking mixture.

Preparing a reference material can be difficult for many manufacturers. It requires specific laboratory equipment and considerable expertise. Therefore, it is possible to use a commercial standard with a known concentration (e.g., MP Biomedicals Gliadin from Wheat, Roquette® Vital Wheat Gluten or Sigma-Aldrich Gliadin) that you will add directly to the extraction solution of your testing kit. It is also possible to buy ready-to-use spiking material such as the Trilogy® Matrix Spike – Gluten or to use the matrix validation services offered by some test kit manufacturers or other competent service providers.

5.2.1.2 *Test the unspiked matrix*

The next step is to test the sample for gluten to confirm that your matrix will not produce a false positive. Follow the test kit instructions and verify that a negative testing result is obtained.

If an unintended positive result is obtained, the sample should be sent to an external laboratory to verify the gluten content with a fully validated quantitative ELISA test. If a positive test result is obtained, it indicates that the sample was contaminated (true positive result). In contrast, if a negative result is received, it indicates that the matrix is cross-reacting with the LFD (false positive result). In this case, contact the test kit manufacturer or use another test kit and repeat the validation process.

5.2.1.3 *Test the spiked matrix*

Spike a sample with a standard gluten material at the desired concentration and verify that the matrix will not interfere with the test kit.

For example, to verify that gluten can be detected at a concentration of approximately 20 ppm, the sample could be prepared as follows:

- Prepare a standard material of 200 ppm or use the Trilogy® Matrix Spike – Gluten.
- Add 1.0 g of the standard material to 9.0 g of ground and homogenized samples.
- Add 100 mL of your extraction solution (ethanol at 60%) to the spiked sample. The dilution ratio is now 1:10.
- Mix the sample thoroughly and follow the test kit instruction for analysis.
- Record the result.

If a positive result is obtained, the test kit can detect gluten in the matrix at the desired concentration. Conversely, if a negative result is obtained, contact the test kit manufacturer or use another test kit and repeat the validation process.

Note that this method can also be used to verify the specific limit of detection (LOD) for the matrix (i.e., the lowest quantity that gives a positive result). To do so, spike your sample at a concentration slightly above the test kit LOD. For example, for a verification at 5 ppm, dilute the 20 ppm solution 1:4 (1+3). For some matrices, the LOD could be different from that specified in the test kit. If a negative result is obtained, increase the spiking level by appropriate increments until a positive result is achieved. This will provide the kit's detection limit for this type of matrix.

5.3 Validate cleaning procedures (non-dedicated facilities only)

Cleaning procedures must be validated to confirm that changeover practices are consistently effective in removing gluten, especially in non-dedicated facilities. It is important to remember that cleaning procedures which are satisfactory for microbiological safety may not be adequate for removing gluten. Furthermore, only degreasers can eliminate gluten – sanitizers are not effective.

A validation study implies a combination of visual inspection of food contact surfaces, swabs taken before and after cleaning, and analysis of samples taken from the subsequent production run (i.e., beginning, middle, and end of production). Testing should always be conducted using specific and validated methods. The number of swabs and locations to be sampled depend on the cleaning and production practices but should cover all aspects of cleaning (e.g., type of residue, type of surface, cleaning methods). When validating cleaning methods, the most difficult places to clean should be swabbed, since they are at higher risk.

Validation should be carried out on three consecutive production runs and reviewed when necessary (e.g., when introducing changes to product formulation or manufacturing equipment and tools) and ideally annually. All results should comply for the validation to be considered successful. If the validation fails, then the risk assessment and cleaning procedures need to be reviewed.

Conclusion

This guide has demonstrated that sampling procedures and testing methods have a significant impact on gluten testing results. An appropriate sampling plan must be developed based on risk assessment. Risk assessment helps manufacturers to determine adequate sampling parameters when building the sampling plans needed to support a GFMS.

In a dedicated facility where no gluten ever enters the production or storage areas, manufacturers should:

- confirm the gluten-free status of incoming materials (ingredients, packaging materials, processing aids, non-food chemicals, etc.)
- confirm that incoming materials have not been cross-contaminated during distribution, storage, or transportation (e.g., spillage)
- control the risk associated with personnel, contractors, and visitors
- validate the gluten-free status of processes and finished products.

In a non-dedicated gluten-free facility where both gluten-containing and gluten-free ingredients are present, manufacturers should also control the risk of contamination at each processing step, from receiving to shipping. Routine check procedures (e.g., swabbing surfaces, testing rinse water) should be put in place during the at-risk steps.

Food manufacturers should select the testing methodology most appropriate for their needs according to the type of product being analyzed and the type of contamination suspected. Even though most regulations do not specify how manufacturers should verify the absence of gluten in their products, government agencies recognize that testing is an essential tool for good manufacturing practices. Manufacturers should interpret testing results with care if they want to ensure that gluten-free claims are

truthful and not misleading, and that their claims comply with all regulatory requirements or their corporate internal limit, which may be more restrictive (e.g., <5 ppm, 10 ppm or other <20 ppm).

Since food matrices can have a significant impact on analytical results, each matrix should be validated. When samples are sent to an external laboratory, be sure to select a laboratory that has fully validated its methods at its site and has achieved ISO 17025 accreditation from a competent authority. Validation ensures that the results obtained are specific and accurate.

It is important to understand that gluten-free compliance should not rely solely on finished product testing. Manufacturers should focus on incoming materials and processing steps, in addition to the finished product, to better manage the risks of contamination. A preventive gluten-control system supported by validated gluten testing is the best way to ensure product compliance.

Schedule 1 Hazard assessment matrix for incoming materials

Ease of detection vs likelihood of occurrence

	Ease of detection			
Likelihood of occurrence	1	2	3	4
	2	4	6	8
	3	6	9	12
	4	8	12	16

Assessment

Score	Ease of detection	Likelihood of occurrence
1	Gluten is extremely easy to detect	Extremely unlikely to contain gluten
2	Gluten is easy to detect	Likely to contain gluten
3	Gluten is difficult to detect	Somewhat likely to contain gluten
4	Gluten is extremely difficult to detect	Very likely to contain gluten

Level of risk

	Low risk	Medium risk	High risk
Score	1–4	6–9	12–16
Color chart			

Evaluation factors

Ease of detection	Likelihood of occurrence
Presence of interfering food components	Nature of the ingredient
Processing steps	Risk of cross-contamination
Physical form of the sample (solid, liquid, powder)	Testing result history
Ease of sampling	Supplier gluten control practices

Schedule 2 Evaluation of likelihood of occurrence per product category

This tool will help you evaluate the occurrence (i.e., the probability that an ingredient contains gluten) of various ingredients used in the food industry. Please note that the following lists are not exhaustive and are provided for information purposes only. During the risk assessment, you must always check the list of ingredients. Furthermore, your risk assessment must be performed in conjunction with a review of the test results and your supplier's evaluation.

Very likely to contain gluten

The following ingredients are prepared from a gluten-containing cereal and should not be used for the production of gluten-free products:

- barley bran
- barley or malt flour
- barley or wheat flakes
- beer, ale, porter, stout
- brewer's yeast
- bulgur
- couscous
- graham flour
- hydrolyzed wheat/barley protein
- malted barley, malted barley flour
- malted beverages or milk
- malt extract
- malt flavoring
- malt syrup
- malt vinegar
- orzo

- rye flour
- tabbouleh
- toasted wheat crumbs
- triticale
- wheat bran, wheat bran hydrolysate
- wheat flours and starches (e.g., atta, dinkel, durum, einkorn, emmer, farina, farro, fu, kamut, spelt)
- wheat germ
- wheat germ oil
- wheat grass.

Gluten is highly likely to be found in ingredients manufactured from oats because of the elevated risk of cross-contamination with other cereals. Use only ingredients manufactured from specially produced gluten-free oats. Check that the company uses processing steps that make it possible to prevent contamination and eliminate gluten (e.g., purity protocol, cleaning/sorting). Ingredients manufactured from oats should contain <20 ppm of gluten and be tested using an appropriate method. Ingredients include:

- β-glucan
- oat bran
- oat extract
- oat fiber/oat hull fiber
- oat flakes/rolled oats
- oat flour
- oat groats
- oatmeal.

Likely to contain gluten

Some ingredients are considered gluten-free by most regulatory organizations regardless of the source, because processing normally eliminates the proteins. However, some private gluten-free certification programs (e.g., GFCP) may not authorize them if they have been derived from gluten sources because other alternative gluten-free sources are available and testing results are difficult to interpret and prone to false negatives. For these ingredients, you should check the source with the manufacturer as well as the measures in place to control the risk of contamination. These ingredients should contain <20 ppm of gluten and be tested using an appropriate method. Examples of ingredients include:

- caramel coloring
- citric acid
- dextrose, glucose, and other -oses
- distilled alcoholic beverages (e.g., gin, vodka, whisky)
- ethanol
- glucose syrup
- maltodextrin
- sugar alcohol (e.g., sorbitol, isomalt, lactitol, maltitol, mannitol, xylitol).

Some product categories are likely to contain gluten. You should read the list of ingredients of these products attentively as well as the measures put in place by the supplier to control the risks of contamination. The product categories include:

- baby food
- bacterial culture[4]
- baked beans
- baked goods
- baking powder[5]
- breakfast cereals
- bouillon
- candy and chocolate candies (e.g., licorice)
- cheeses[6]
- coloring agents (e.g., caramel)
- condiments (e.g., barbecue sauce, curry paste, dressing, ketchup, mirin, miso, pickles, prepared mustard, soy sauce, tamari sauce, teriyaki sauce, Worcestershire sauce, etc.)
- flavored ice cream
- flour mixes
- French fries
- gravy
- icing, frosting
- imitation fish (e.g., surimi)
- instant coffee
- koji
- mustard flour
- rice mixes
- rice syrup, rice vinegar
- sauces
- seasonings
- smoke flavoring (e.g., liquid smoke, smoke seasoning, smoke powder)
- snack foods
- soups
- sprinkles
- pasta, noodles
- prepared meat (cold cuts, lunch meats, sausage, etc.)
- pudding
- yeast (e.g., active dry, baker's, nutritional, torula).[7]

4 Check the substrate used because bacterial cultures are sometimes grown on rye grains, malt or wheat starch.

5 Check for wheat starch

6 Some cheeses might contain gluten (e.g., blue cheese, flavored cheeses, shredded cheeses, cheese spreads) and cross-contamination is possible when handled or packaged in stores.

7 Sometimes made on a gluten-containing medium.

Somewhat likely to contain gluten

Some ingredients can be made from a gluten-containing cereal or from a gluten-free source. The source of these ingredients must be confirmed with the processor. Ingredients manufactured from a cereal containing gluten should not be used in a gluten-free formulation unless the manufacturer is able to show that the ingredient was processed to eliminate the gluten. However, some private gluten-free certification schemes (e.g., GFCP) may not authorize them if they have been derived from gluten sources because alternative gluten-free sources are available. Moreover, test results are usually difficult to interpret or may be deceptive. These ingredients should contain <20 ppm of gluten and be tested using an appropriate method. Examples of ingredients include:

- autolyzed yeast
- dextrin
- food starch and modified food starch
- fermented beverages
- hydrolyzed proteins
- vitamin E/tocopherol
- yeast extract
- yeast.

Agricultural products that are inherently gluten-free may be contaminated by cereals containing gluten during planting, cultivation, harvesting, transport, processing, etc. For these ingredients, you must ask your suppliers what controls are in place to prevent cross-contamination. These ingredients must contain <20 ppm of gluten and be tested using an appropriate method. For example, products (flours, grains, starch, flakes, etc.) derived from the following agricultural products must be tested:

- acorn
- amaranth
- arrowroot
- buckwheat (not in the wheat family)
- cassava
- chestnut
- corn
- manioc
- millet
- potato
- pulses (beans, chickpeas, fava beans, lentils, peas, etc.)
- quinoa
- rice (glutinous, wild, etc.)
- seeds (chia, flax, hemp, pumpkin, sesame, sunflower, etc.)
- sorghum
- soy
- spices and herbs
- sweet potato
- tapioca
- teff.

Extremely unlikely to contain gluten

The following ingredients are generally free from gluten. Nonetheless, verifying the list of ingredients as well as the measures put in place by the supplier to control the risk of cross-contamination is recommended. Ingredients include:

- additives
- egg products
- baking soda
- chocolate and cocoa
- coffee
- coconut by-products
- cream of tartar
- food gums (agar-agar, carrageenan, cellulose, guar, locust bean, pectin, xanthan, etc.)
- fish and seafood
- fruits and vegetables (fresh, frozen, canned, juice)
- meat and poultry
- milk products (butter, buttermilk, cream, sour cream, unflavored yogurt)
- nuts
- oil and fats (e.g., lard, margarine, shortening, vegetable oils)
- water
- gelatin
- inulin
- lecithin
- mono and diglycerides
- pure and artificial flavors (e.g., monosodium glutamate, vanilla)
- salt
- sugars and sweeteners (e.g., acesulfame potassium,agave syrup, aspartame, brown sugar, cane sugar,corn syrup, fructose, honey, icing sugar, maple syrup, molasses, stevia, etc.)
- tea
- tofu (plain)
- wine[8]
- vinegar (e.g., apple cider, balsamic, distilled white, red wine, white wine)

8 Check the type of fining agent used.

Schedule 3 Hazard assessment matrix for processing steps

Severity vs likelihood of occurrence

	Severity			
Likelihood of occurrence	1	2	3	4
	2	4	6	8
	3	6	9	12
	4	8	12	16

Assessment

Score	Severity	Likelihood of occurrence
1	Low	Rare
2	Medium	Occasional
3	High	Common
4	Very high	Very common

Level of risk

	Score	Color chart
Low risk	1–4	
Medium risk	6–9	
High risk	12–16	

Schedule 4 The specific case of oats

Composition

Oats are recognized as being structurally different from other gluten-containing cereals such as wheat, rye, barley, and their hybrids. Oat proteins are primarily composed of globulins (70–80%). Oat prolamins, known as avenins, are present in an extremely low concentration, i.e., 4–14%, which may in part explain their low toxicity for people with celiac disease. It is generally recognized that specially prepared gluten-free oats do not represent a risk for gluten-sensitive individuals, although health professionals and regulatory organizations recommend gradually integrating oats into a gluten-free diet under medical supervision.

The amino acid sequences of avenins contain less proline (P) and glutamine (Q) than wheat gliadins, barley hordeins, and rye secalins. This has the positive effect of making them almost undetectable by most ELISA test kits.

Cross-contamination risk

Regular oats are frequently contaminated by other grains containing gluten because they are often grown in the same fields or in proximity to wheat, rye, and barley crops. The purity of the seeds used by producers can also be an issue. Lastly, suppliers sometimes use the same equipment to sow, harvest, transport, store, process, and package these cereals.

Producers of gluten-free oats must ensure that their product meets regulatory requirements at all times (i.e., 20 ppm or less gluten). To do so, producers have several options available to them.

One of these options is the use of purity protocol. A purity protocol is composed of documented control measures with the objective of reducing the risk of gluten contamination in all processing steps. It involves several procedures including the use of pure seeds, field management, cleaning and inspecting equipment, grain sampling, etc.

Gluten-free oats can also be obtained after mechanically and optically sorting grains based on their size, shape, color, and density. However, because of the elevated risk of contamination, these practices must be carefully validated before confirming that the

product is gluten-free and safe for people with celiac disease. The combination of a purity protocol and optical sorting techniques considerably increases the likelihood of obtaining a gluten-free product.

Thus, when you want to buy gluten-free oats, it is essential that you ask suppliers about their control measures, testing frequency, the tests used for analysis, testing results, etc.

Schedule 5 Comparison of commercially available ELISA and LFD test kits

Comparison 1

Test kit	Aller-Tek Gluten ELISA	Wheat/gluten (gliadin)	Veratox® for Gliadin	Veratox for Gliadin R5	RIDASCREEN® Gliadin
Manufacturer	ELISA Technologies	Morinaga Institute	Neogen	Neogen	R-Biopharm
Method	Sandwich ELISA	Sandwich ELISA	Sandwich ELISA	Sandwich ELISA	Sandwich ELISA
Type of results	Quantitative	Quantitative	Quantitative	Quantitative	Quantitative
Reference material	Wheat gluten and barley standard available	NIST SRM 1567a – wheat flour	Gliadin G3375 (Sigma-Aldrich)	Gliadin G3375 (Sigma-Aldrich)	PWG gliadin
Antibody	Skerritt monoclonal (401.21)	Anti-gliadin polyclonal antibody	Skerritt monoclonal (401.21)	R5 monoclonal	R5 monoclonal
Extraction protocol	40% ethanol with extraction mix	Specific extraction solution	40% ethanol or cocktail solution	60% ethanol or cocktail solution	60% ethanol or cocktail solution
Interval of quantification (ppm gluten)	5–80 ppm	0.26–68 ppm	10–100 ppm	5–80 ppm	5–80 ppm
Limit of detection (LOD) (ppm gluten)	5 ppm	0.26 ppm	10 ppm	2.2 ppm	1 ppm
Validation	AOAC-RI 081202	Interlaboratory study supported by the Japanese Ministry of Health, Labor and Welfare	Not available	AOAC-RI 061201	AOAC-OMA 2012.01AOAC-RI 120601AACCI 38.50.01 Codex Alimentarius reference method (Type I)
Usage	Processed and unprocessed food products, environmental surfaces	Processed and unprocessed food products, environmental surfaces	Processed and unprocessed food products, environmental surfaces	Processed and unprocessed food products, environmental surfaces	Processed and unprocessed food products, environmental surfaces
Other specifications	It underestimates barley	High recovery of gluten for processed foods Used by the FDA for gluten-free products (in tandem with RIDASCREEN® Gliadin kit) It underestimates barley and rye	It is generally no longer in use, since it has been replaced by the R5 test kit	It overestimates barley and rye	It overestimates barley Used by the FDA for gluten-free products (in tandem with Morinaga wheat/gluten [gliadin] kit)

Comparison 2

Test kit	AgraQuant®	RIDASCREEN® Gliadin competitive	GlutenTox® Pro	GlutenTox® Sticks Plus	EZ Gluten®
Manufacturer	Romer Labs®	R-Biopharm	Biomedal Diagnostics	Biomedal Diagnostics	ELISA Technologies
Method	Sandwich ELISA	Competitive ELISA	Lateral flow device	Lateral flow device	Lateral flow device
Type of results	Quantitative	Quantitative	Semi-qualitative	Semi-quantitative or quantitative	Qualitative
Reference material	VWG gliadin	Hydrolysate mixture of wheat, rye and barley	N/A	N/A	N/A
Antibody	G12 monoclonal	R5 monoclonal	G12 monoclonal	G12 monoclonal	Skerritt monoclonal (401.21)
Extraction protocol	60% ethanol or cocktail solution	60% ethanol	Universal Gluten Extraction Solution (UGES)	UGES	Extraction buffer
Interval of quantification (ppm gluten)	4–200 ppm	10–150 ppm	N/A	8–85 ppm	N/A
Limit of detection (LOD) (ppm gluten)	2 ppm	2.7 ppm	Samples: 5, 10, 20 or 40 ppm Swabs: 16 ng/16 cm^2	Samples: 3, 10, 20, 30 or 100 ppm Swabs: 16 ng/16 cm^2	Samples: 10 ppm Swabs: 1 µg/25 cm^2
Validation	AACCI 38.52.01AOAC-OMA 2014.03	AACCI 38.55.01AOAC-OMA 2015.05	AOAC-RI 061502	Validated by FAPAS and AESAN only (Spain)	AOAC-RI 051101
Usage	Processed and unprocessed food products, environmental surfaces	Hydrolyzed and fermented food products	Lightly processed and unprocessed food products, environmental surfaces	Lightly processed and unprocessed food products, environmental surfaces	Lightly processed and unprocessed food products, environmental surfaces
Other specifications	It detects some oat varieties suspected to trigger a response in people with celiac disease	It can also be used to detect intact and unprocessed proteins It cannot be used with the cocktail solution	It should not be used for matrices with a high content of polyphenols and tannins It detects some oat varieties (suspected to trigger a response in people with celiac disease)	It detects some oat varieties (suspected to trigger a response in people with celiac disease) Quantitative results can be obtained in combination with the GlutenTox® reader	It underestimates barley

Comparison 3

Test kit	AllerFlow Gluten	Reveal® 3-D	Alert® for Gliadin R5	RIDA®QUICK Gliadin	AgraStrip®
Manufacturer	Hygiena	Neogen	Neogen	R-Biopharm	Romer Labs®
Method	Lateral flow device	Lateral flow device	ELISA	Lateral flow device	Lateral flow device
Type of results	Qualitative	Qualitative	Qualitative	Qualitative	Semi-qualitative
Reference material	N/A	N/A	N/A	N/A	N/A
Antibody	G12 monoclonal	Proprietary	R5 monoclonal	R5 monoclonal	G12 monoclonal
Extraction protocol	Extraction solution with reducing and dissociating agents	Extraction solution	80% ethanol or cocktail solution	60% ethanol or cocktail solution	60% ethanol
Interval of quantification (ppm gluten)	N/A	N/A	N/A	N/A	N/A
Limit of detection (LOD) (ppm gluten)	Swabs: 5 µg/100 cm^2	Samples: 5 ppm Swabs: 80 µg/100 cm^2	Sample: 20 ppm Swabs: 1–2 µg/100 cm^2	Samples: 5 ppm Swabs: 2–4 µg/100 cm^2	Samples: 5, 10 or 20 ppm Rinse water: 35 ppb Swabs: 4 µg/25cm^2
Validation	Internal validation	Internal validation	Internal validation	AOAC-OMA 2015.16 (AACCI in process)	AOAC-RI 061403
Usage	Environmental surfaces and rinse water	Environmental surfaces and rinse water	Lightly processed and unprocessed food products, environmental surfaces and rinse water	Processed and unprocessed food products, environmental surfaces, CIP water	Lightly processed and unprocessed food products, environmental surfaces and rinse water
Other specifications	Similar to Biomedal's GlutenTox® It detects some oat varieties				It detects some oat varieties

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