



710 Striker Avenue, Sacramento, CA 95834 (Tel. 916-246-2816)

Gluten- Free Certification Guide & Terms of Certifications

Gluten and Celiac Disease

Over 3 million North Americans may have celiac disease and another 30 million may suffer from gluten sensitivity. Celiac disease is a hereditary autoimmune disease triggered by consuming gluten protein that causes the immune system to attack the lining of the small intestine, affecting absorption of nutrients. The disease leads to malnutrition and conditions such as anemia, osteoporosis, neurological disorder, cancer, etc. There is no cure and the only treatment is a strict gluten-free diet for life which, up until now, has been difficult.

What is Gluten?

Gluten is the protein that occurs naturally in Rye, Barley, Wheat, Triticale, Oats (except gluten free oats - Canada only – specifically produced with agronomic and handling practices designed to ensure that the oats contain no more than 20 PPM gluten) and any modified gluten protein fraction (or ingredient) including hybridized grain strain; these are the major sources of gluten protein for people suffering with Celiac disease.

What foods contain gluten?

Foods that typically contain gluten include, among others, breads, cakes, cereals, pastas, and many other foods.

In order to be granted the gluten-free dietary designation, the final product should contain less than 20 PPM of gluten. Various AOAC methods for gluten residue testing are available with certain testing limitations.

Foods that can be labeled as “Gluten-Free”

Whether a food is manufactured to be free of gluten or by nature is free of gluten, it may bear a “gluten free” labeling claim if it meets all FDA requirements for a gluten-free foods.

Some foods and beverages, such as bottled water, fruits, vegetables, and eggs are naturally gluten-free. However, because a “gluten free” claim is not required (it is voluntary) to be on a food package, it may not appear even if the food is “gluten-free”

Allergen Control Group (ACG) and Gluten-Free Certification Program (GFCP)

The Gluten Free Certification Program (GFCP), a product certification program, is owned and operated by Allergen Control Group (ACG), and has been accepted by US and Canadian regulators (e.g., Health Canada, CFIA, FDA and USDA). ACG’s Gluten Free Certification



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program is also endorsed by two leading celiac organizations in North America, the Beyond Celiac (BC) and the Canadian Celiac Organization (CCA).

The GFCP is a HACCP-based certification program with required PRPs (pre-requisite programs) and GMPs (Good Manufacturing Practices) to support HACCP implementation to achieve intended objectives. However, the requirements may vary based on the type of a facility and nature of gluten-free products that a particular facility is processing as noted (under the title, "Type of facilities certified under GFCP").

Advantages of Gluten-Free Certifications

The Gluten-free certification program is a voluntary program designed specifically for manufactures and brand owners (who are committed) to assist in manufacturing safe and reliable gluten-free products. The program combines stringent and risk based robust gluten free requirements with recognized food safety systems which may exceed the regulatory requirements in North America. The certification program is verified annually by the third party facility audit process that ensures continued compliance to the program. The consumers can buy products with confidence and knowing that the products they purchase meet the industry's strictest gluten free requirements when they see the GFCP trademark.

Type of facilities certified under GFCP

- **Dedicated Gluten-Free facility** where no gluten ever enters the facility storage or production areas. Dedicated gluten-free facility must have documented GMPs (HACCP plan is optional).
- **Non-dedicated or shared gluten facility** where both gluten and non-gluten containing products are present and or processed. Non-dedicated facilities must have documented GMPs and a functional HACCP plan that identifies gluten as a chemical hazard.



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GFCP Audit Types of Functions

GFCP certification program conducts two types of audits:

Combined Audit:

Companies which may be audited under recognized private food Safety Standards and audit protocols (such as SQF, BRC, HACCP, GMP, etc.). The auditor will follow the audit plan for that standard when combined with GFCP requirements.

Standalone Audit:

Companies which are not audited under a recognized standard and audit protocol and are only seeking GFCP certification.

GFCP Documents for Certifications

1. The certification audit is conducted against the GFCP audit checklist (audit template).
2. GFCP certification program is a Codex based HACCP (Hazard Analysis and Critical Control Points) system and is supported by PRPs (Pre-requisite programs) and GMPs (Good Manufacturing Practices).
3. Policies and procedures for the HACCP system, PRPs and GMPs--including management commitment--are key to successful implementation of program
4. The monitoring, verification and validation records to demonstrate that the food safety system (policies and procedures), if implemented correctly, is capable of preventing, eliminating or reducing hazards to an acceptable level.
5. A minimum of 90 days of records is required at the time of audit to review and determine the facility compliance to a HACCP system.

Training & Document Requirements for GF Certification

1. Learn the GF Requirements (training recommended) identified by GFCP.
2. Documented policies and procedures – develop HACCP program with PRPs and GMPs if a non-dedicated facility; and GMPs (optional HACCP) for a dedicated facility (i.e., an exclusive gluten-free processing facility).



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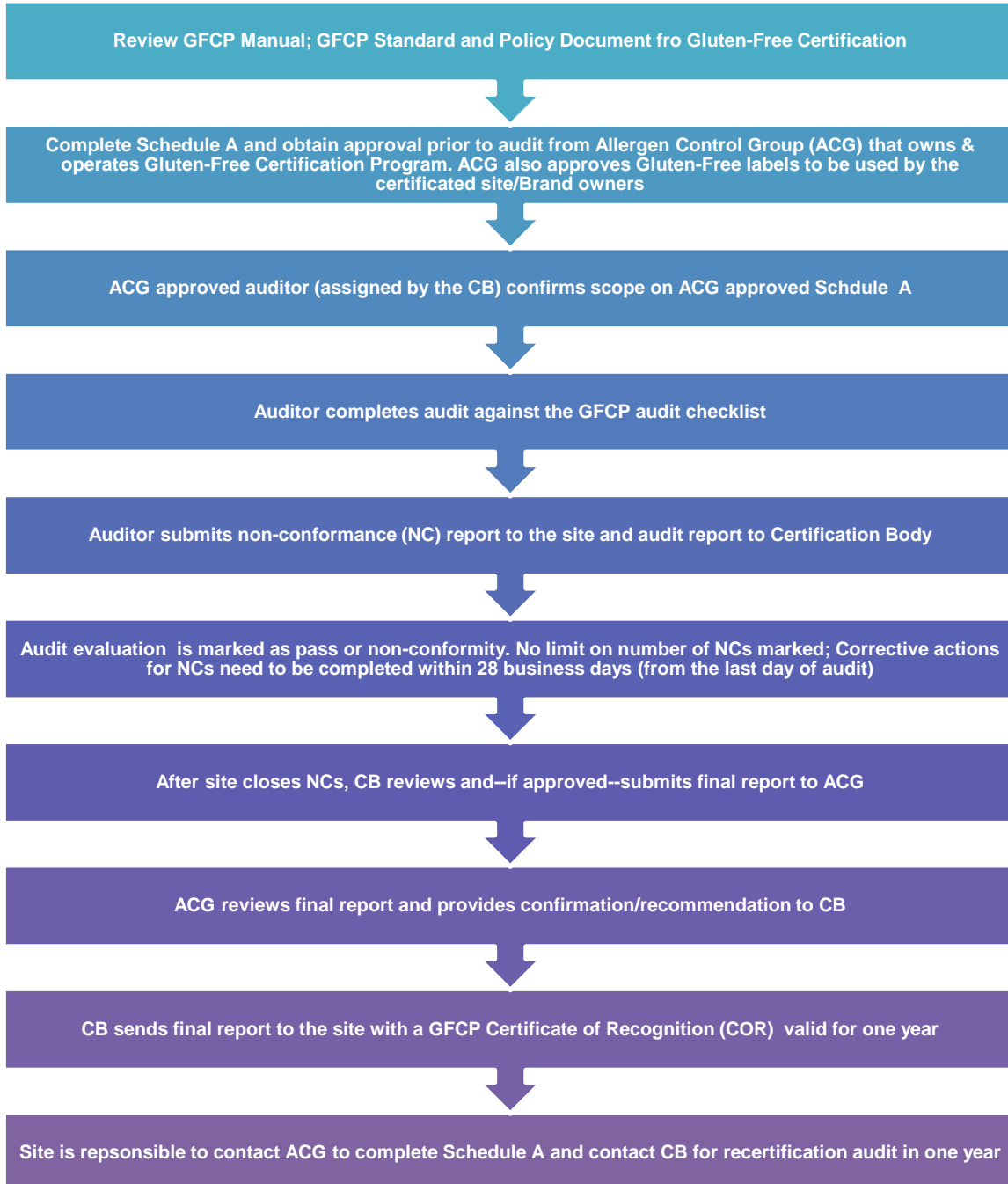
3. Create record forms and have at least 3 months of records at the time of a certification audit.
4. Pre-assessment by an expert third-party (recommended).
5. Implement and verify corrective actions.
6. Register with Allergen Control Group for Gluten Free Certification Program.
7. Complete Schedule A and submit to Allergen Control Group for their review and approval prior to the audit.



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Overview of Gluten-Free Certification Process





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Application Process

- ✓ Register with Allergen Control Group for Gluten Free Certification Program.
- ✓ Contact Safe Food Certifications for the Company Profile Application for Gluten Free certification; complete the questionnaire and return to Safe Food Certifications.
- ✓ Complete Schedule A and submit to Allergen Control Group for their review and approval.
- ✓ ACG will review Schedule A, approve and sign the Schedule A. ACG will also approve the Gluten-Free labels for the manufacturer or brand owner to use.
- ✓ Safe Food Certifications will review company profile questionnaire to:
 - Confirm scope of Gluten-Free certification; scope shall not reference any specific products to be certified;
 - Determine audit category and audit duration;
 - Assign a GFCP certified auditor;
 - Suggest tentative dates for audit; and
 - Provide a quote for certification services and certification service agreement to be signed by the site prior to the audit.

Audit Procedure

Refer to detailed gluten-free certification audit process outlined in the certification process flow chart above.

1. A GFCP certified auditor is assigned to conduct audit.
2. Auditor conducts opening meeting to indicate the scope of the audit and protocols to be followed during the audit.
3. A key personnel form is used to document company/site management present for the opening meeting, throughout the audit process and closing meeting.

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4. Auditor reviews Schedule A to ensure that it is duly signed by ACG prior to beginning the audit.
5. GFCP category on approved Schedule A should be in production at the time of audit and production records for at least 90 days should be available.
6. The final report approved by ACG includes:
 - Company profile with relevant company details;
 - Audit Checklist and guidance; audit evaluation marked as either “Pass or NC”
7. Audit checklist includes objective evidence or comment for each requirement, clearly written and “actionable” non-conformity details. There is no limit on number of non-conformities assigned as long as they are satisfactorily completed to meet requirements within twenty eight (28) business days from the last day of audit.
8. Auditor explains non-conformity when it is observed during the audit to the site designated lead.
9. Auditor conducts closing meeting to provide an overall audit evaluation and explains each non-conformity assigned.
10. Auditor provides a summary of non-conformities, signed and dated, to the site-designated lead.
11. Auditor provides report to the CB and is also responsible to review, complete, and approve non-conformities within twenty-eight (28) business days (from the last day of audit).
12. CB to review complete report with completed NCs and submit to ACG for a final approval.
13. ACG reviews final reports and submits to CB with final recommendation with a certificate of recognition (COR) number to CB.
14. CB submits final report with a Certificate of Recognition (COR) to the certificated site. The COR is valid for one (1) year.
15. Certificated site is responsible to use Gluten-Free logos approved by ACG meeting the specified requirements.
16. Certificated site is responsible to initiate recertification process (recommended - 2 months prior to the expiration of certificate) by contacting ACG and completing Schedule A, and contacting Safe Food Certifications.

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Terms of Gluten-Free Certifications

Use of GFCP Trademark

1. The prescribed trademark designs set out in GFCP's schedule 1 can be used;
2. The GFCP trademark must be prominently and indelibly applied to the labels of all packaged products and shipping containers where practical;
3. When GFCP trademark is placed on a label, it shall have no transverse measurement through the center of the trademark of less than 10 mm (0.4 inches);and
4. No licensee (Certificated site under the GFCP) shall identify as gluten-free any product intended for export unless the product meets the regulatory requirements of the importing country and those of the GFCP.

Suspension of Program License Agreement

The ACG President can suspend license of the GFCP certificated facility if:

1. Facilities certified under the GFCP and supplying product do not comply with the requirements of the GFCP, the GFCP manual or any other relevant act or regulations; and failed to implement corrective actions satisfactorily; or
2. It is reasonable to believe that public health will be endangered through consumption of products produced under the name of certified facility if the license is allowed to continue.

The suspension of GFCP certified facility shall remain in effect:

1. Until the required corrective measures have been implemented and have been verified to the satisfaction of the President of ACG; or
2. If the licensee fails to pay fee (to ACG and CB) prescribed by the GFCP in accordance with the conditions of payment defined by the ACG.



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Gluten- Free Certification Guide & Terms of Certifications Cancellation of Program License Agreement

The ACG President may cancel the license of the GFCP certified facility if:

1. Facilities certified under the GFCP (licensee) have not implemented corrective measures within 90 days after the date on which the license was suspended; or
2. The application for a license contains false or misleading information and it is reasonable to believe that public health will be endangered of through consumption of products produced under the name of certified facility if the license is allowed to continue.

A license of the certified facility may become void if:

1. The recognized/certified facility (ies) are no longer able to supply gluten-free products;
2. The licensee has relocated to an address different from the address stated in the list of licensees;
3. The licensee is a subject to a receivership or makes an assignment in bankruptcy; or
4. The Licensee ceases or is unable to operate under the same terms and conditions of the license or surrenders the license.

References

1. GFCP Standards and policies
2. GFCP Manual
3. Audit Report Template
4. Schedule A