GLUTEN-FREE CERTIFICATION PROGRAM
Manual

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Definitions

“approved auditor” means a person who has met the President’s criteria and is notified to be an authorized service provider as an auditor for the Gluten-Free Certification Program.

“adulterated” means, in respect of a gluten-free product, failing to conform to the USFDA or USDA regulations and particularly exceeding the limits assigned for gluten (i.e. 20 ppm) as determined by government and ACG endorsed official methods;

“advertise” includes the making of a representation by any means whatever for the purpose of promoting, directly or indirectly, the sale or disposal of a gluten-free;

“audit” includes

(a) in respect of any product or other thing, the examination of a sample from a shipment or other collection of products or other things,
(b) in respect of a process, the verification or monitoring of the process, and
(c) the examination of the other information that may be necessary to verify conformance with the requirements of the Gluten-Free Certification Program;

“bulk container” means a container not intended for sale by a retailer to a consumer and includes a shipping container;

“certified” means to be assessed as conforming to the Gluten-Free Certification Program by the President of ACG;

“container” means a package or confining band in which a product is or is intended to be offered for sale, but does not include a lining, a bulk container, or a transport container;

“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;

“drug” has the same meaning as defined by the national, regulatory competent authority;

“facility” is defined as the areas under the accountability of a recognized facility or licensee as per their Gluten-Free Management System.

“food” has the same meaning as defined by the national, regulatory competent authority where the product is sold;

“food additive” has the same meaning defined by the national, regulatory competent authority where the product is sold;

“gluten” means any gluten protein from the grain of any of the following cereals or from the grain of a hybridized strain that is created from at least one of the following cereals:

(a) barley
(b) rye
(c) triticale
(d) wheat
(e) oats except gluten-free oats (Canada only) or
(f) any modified gluten protein, including any gluten protein fraction, that is derived from the grain of any of the cereals referred to in sections (a) to (e) or from the grain of a hybridized strain referred to in those sections.
“gluten-free” shall be as defined by the Gluten-Free Certification Program and the appropriate national, regulatory competent authority where the product is sold.

“Gluten-Free Management System (GFMS)” means a hazard analysis and critical control points plan that is prepared in accordance with the GFCP Manual for a process or product and that specifies, in respect of the process or product, all the hazards especially gluten, critical control points, critical limits, monitoring procedures, deviation procedures, verification procedures and records;

“gluten-free oats” are specially produced and handled oats which have no more than 20 ppm of gluten and must be identified in the common name or in the ingredient listing as gluten-free oats.

“GFCP Manual” means the Gluten-Free Certification Program Manual published by ACG as amended from time to time;

“harmful gluten materials” are peptide sequences or other chemicals derived from any source containing substances such as gliadins or glutenins which are scientifically proven to be harmful to those who have been diagnosed to have celiac disease or otherwise suffer from conditions such as gluten intolerance.

“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 Gluten-Free Certification Program in the absence of its control;

“inedible products area” means that part of a facility in which inedible products are received, held, processed, shipped or otherwise dealt with;

“ingredient” means an individual unit of product that is combined with one or more other individual units of product to form an integral unit of product;

“inspection” means internal testing, examination and/or audit conducted by the operator of a recognized facility or as a requirement of a license.

“license” is the official authorization to use and apply the Gluten-Free Certification Trademark(s) or similar words.

“List of Licensees” means the list maintained by the President of those entities deemed to be licensed in conformance with the Gluten-Free Certification Program and authorized to use the Gluten-Free Trademark(s) on labels and advertising;

“List of Recognized Facilities” means the List of Recognized Facilities deemed to be in conformance with the Gluten-Free Certification Program and maintained by the President;

“operator” means a person who is designated as being accountable for the operation of a recognized facility or the maintenance of a license collectively known as a facility;

“prepackaged” means packaged in a container in the manner in which it is ordinarily sold to or used or purchased by a consumer without being repackaged;

“prepared” means a product that has been subjected to a process such as cutting, blending, packaging, cooking or dehydrating or to which has been added any substance;

“pre-requisite programs” means written programs developed for a facility as applicable in accordance with the GFCP Manual to ensure conformity with the Gluten-Free Certification Program

(a) the premises, including its outside property, buildings and sanitary facilities,
(b) the water, ice and steam quality programs,
(c) the storage and transportation of products, including temperature control and the vehicles for transporting products,
(d) the storage of material, including incoming material, non-food chemicals and finished products including temperature control,
(e) the equipment including the general design, installation, maintenance and calibration of the equipment,
(f) the training, hygiene and health of personnel,
(g) the sanitation and pest control programs, and
(h) recall procedures and distribution records;

“President” means the President of the Allergen Control Group (ACG);

“principal display panel” as defined by the national, regulatory competent authority.

“principal display surface” means as defined national, regulatory competent authority.

“process” means to substantially change the appearance or nature of a product, and includes to slice, comminute, thermally process, preserve, dehydrate, ferment, render, fractionate or add thereto an ingredient permitted to be added by this standard or any government regulation;

“product” is something produced by human or mechanical effort or by a natural process that is purchased and is intended to serve the perceived or actual need of a buyer or consumer.

“recognition” is the official recognition given to a facility that conforms to the Gluten-Free Certification Program.

“recognition number” means the number assigned to a recognized facility under subsection 8(5);

“sanitation program” means a written program to ensure that the buildings, equipment, utensils, transport containers and all other physical facilities of a recognized facility or under the control of a licensee are maintained in a conditions which are deemed to be in conformance with the Gluten-Free Certification Program;

“transport container” includes any conveyance used for the transportation of products;
Section 1 - Gluten-Free Certification Program Description

1.1 Introduction

At the present time, there is no cure for persons suffering from celiac disease or gluten intolerance. Statistically, over 3,500,000 Americans and Canadian may have celiac disease and over 30 million more may suffer from gluten intolerance. The only mitigation option for those who are afflicted is to dedicate themselves to a 100% gluten-free diet which is very difficult within the mainstream food supply in North America.

Research has shown that without a gluten-free diet, the longterm affects can lead to very serious health consequences. It is generally understood and accepted by the USFDA and the USDA that the claim “gluten-free” relegates the product into an area generally known as “food for special dietary use” and describes gluten and gluten-free products under the GFCP as follows:

“gluten” means

(a) any gluten protein from the grain of any of the following cereals or from the grain of a hybridized strain that is created from at least one of the following cereals:

   (i) barley,
   (ii) rye
   (iii) triticale
   (iv) wheat
   (v) oats except gluten-free oats (Canada only) or

(b) any modified gluten protein, including any gluten protein fraction, that is derived from the grain of any of the cereals referred to in paragraph (a) or from the grain of a hybridized strain referred to in that paragraph.

Also:

It is prohibited to label, package, sell or advertise a food in a manner likely to create an impression that it is a gluten-free food if the food contains any gluten protein or modified gluten protein, including any gluten protein fraction, referred to in the definition “gluten”

The ACG and the CCA and the BC encourage producers, manufacturers and distributors to make gluten-free flours, baked goods, pasta products, breakfast cereals as well as other single and multi-ingredient foods more credible, identifiable, nourishing and available. However no recognized, generic model or standard operating procedures exists in the USA or anywhere else in the world.

In order to assist industry, the ACG took the lead in the development of a Gluten-Free Certification Program. To do this, it developed a voluntary process to recognize facilities and issue licenses to use a certification trademark. In addition, it has developed tools to support the program such as manuals, training, approval of auditors, piloting, industry consultation etc. to implement a self-sustaining certification program with distinctive GFCP Trademarks signifying has come from a certified facility which has demonstrated its ability to prove that it has the consistent capacity to produce “gluten-free” products. Therefore, the ACG is inviting producers, manufacturers and distributors to participate under the Gluten-Free Certification Program. Producers and manufacturers will be evaluated and audited to become recognized facilities and they as well as distributors will be licensed to use and apply the Gluten-Free Certification Program Trademarks Trademark(s) knowing that products bearing the Gluten-Free Certification Program Trademark(s) must be sourced from a recognized facility.
The ACG believes that following Hazard Analysis of Critical Control Points (HACCP) or HACCP-based product safety systems is the best approach. It intends to continue to improve the program by working with all stakeholders including industry, governments and consumers to better the Gluten-Free Certification Program.

1.2 Types of product safety hazards controlled by a Gluten-Free Management System

The ACG supports product safety and HACCP principles to control physical, chemical and biological hazards. Although the Gluten-Free Certification Program addresses gluten as a chemical hazard and will certify recognized facilities which meet minimum good manufacturing practices and produce safe, gluten-free products. Most reputable manufacturers and distributors have pre-requisite programs and other systems in place to prevent product safety failures from happening. ACG 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 gluten-free products that come from facilities certified under the GFCP.

1.3 Benefits of Gluten-Free Management System

The long-term outcome of the Gluten-Free Certification Program is to promote the concept of a systems approach to prevent failures that could harm the public. Correctly applied, a company’s Gluten-Free Management System will provide a very strong level of protection from failure and if failure does occur to be able to rapidly identify and manage suspect product. The resulting effect will be that industry will be able to expand markets, increase the availability of gluten-free products which achieve regulatory requirements while hopefully reducing the burden on government enforcement. Consumers would benefit by the increased confidence, recognition at point of purchase, availability and variety of choice.

Section 2 - Responsibilities

2.1 ACG responsibilities

- Will develop and maintain a voluntary, Gluten-Free Certification Program in consultation with consumers, industry and government stakeholders. Consideration will be given to harmonize with best approaches that others have been developed and successfully implemented.

- Recognize the systems of manufacturers and distributors who conform to the requirements of the Gluten-Free Certification Program

- Verify the implementation, effectiveness and maintenance of the Gluten-Free Management Systems that manufacturers and distributors have in place

- Provide competent staff for the recognition and verification of Gluten-Free Management Systems developed and implemented by recognized facilities

- 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 program.

- Consider any information presented in the conduct of the program such as copies the Gluten-Free Management System documentation that are obtained by an officer or auditor under the Gluten-Free Certification Program to
be private and confidential and shall protect the information to the extent of the law. The ACG will request only information which is relevant to the administration of the Gluten-Free Certification Program.

• The ACG is a private organization and should not be considered to be equivalent to a regulatory agency.

2.2 Facility responsibilities

2.2.1 Facility senior management commitment

• Ensure that the facility complies with the requirements of the Gluten-Free Certification Program.

• Ensure that the facility's Gluten-Free Management System conforms with all the requirements identified in the GFCP Standards and Policies Document Respecting the Certification of Gluten-Free Products and the supporting Gluten-Free Certification Program Manual.

• Demonstrate a commitment to their Gluten-Free Management System by:
  - providing the necessary resources and the time required for the development, implementation and effective maintenance of the Gluten-Free Management System 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 Gluten-Free Management System;
  - designating personnel that have defined responsibilities and the authority to initiate, implement and record corrective actions;
  - communicating to employees the importance of meeting the requirements of the facility's Gluten-Free Management System including any regulatory requirements related to product safety and gluten control, and the importance of reporting problems to the identified person(s);
  - allowing designated management personnel to enforce conformity of the product safety procedures identified in the facility's Gluten-Free Management System for any person entering or working within the facility;
  - allowing the continuous improvement of the Gluten-Free Management System to ensure its effectiveness through the validation of control measures, by making changes to the system as a result of corrective actions or reassessment activities, and through the use of Gluten-Free Management System Team meetings;
  - providing sufficient time for Gluten-Free Management System Team meetings.

• Ensure all information and documentation is accessible to persons designated by the ACG during evaluation processes and subsequent verification/audit activities.

A letter of commitment shall be included in the Gluten-Free Management System documentation. The letter of commitment shall be signed and dated by a representative of senior management at the facility with authority to ensure adherence to responsibilities described in this section. The letter shall be renewed on an annual basis or when that senior manager is replaced. The letter must:
• confirm senior management’s full support for developing, implementing and maintaining an effective Gluten-Free Management System;
• confirm the facility’s commitment to produce product in conformity with all of the requirements of the ACG Gluten-Free Certification Program.

2.2.2 Gluten-Free Management System Team Leader

Senior Management shall appoint a Gluten-Free Management System Team leader who, irrespective of other responsibilities, shall have the responsibility and authority:

• to ensure that the Gluten-Free Management System is developed, implemented, maintained and reassessed;
• to be the main contact with designated staff and auditors approved by the ACG.

Note: It is recommended that the Gluten-Free Management System Team leader be on the premises on a regular basis. Where the Gluten-Free Management System leader is not at the recognized facility on a regular basis, an on-site liaison person must be identified to take on these responsibilities and authorities.

2.2.3 Gluten-Free Management System Team

The Gluten-Free Management System Team consists of assigned personnel that have adequate knowledge and or experience. Representing various areas within a facility such as production, sanitation, quality control, microbiology and equipment maintenance, they are responsible for assisting the Gluten-Free Management System Team leader in developing, implementing and maintaining the Gluten-Free Management System.

The number of people on the Gluten-Free Management System Team may vary based on the complexity of the process and the number of employees at the facility. In small plants with a limited number of staff, the Gluten-Free Management System Team may be made up of people who have a good understanding of the facility and its products, as well as HACCP principles.

The Gluten-Free Management System Team should meet on a regular basis to discuss, among other points:

• Changes in the Gluten-Free Management System
• Deficiencies in the Gluten-Free Management System
• Root causes
• Action plans
• Reaction to non-conformities found by GFCP Approved Auditors

It is recommended that representatives from senior management participate periodically in Gluten-Free Management System Team meetings to be aware of the Gluten-Free Management System performance within their facility.

2.2.4 Competency

The Gluten-Free Management System Team leader should, at a minimum, be knowledgeable of:

• Product safety hazards common to the facility’s products and processes
• Applicable regulatory and the Gluten-Free Certification Program requirements
• Requirements of the company’s Gluten-Free Management System
• HACCP principles and science-based approaches.
The Gluten-Free Management System Team should be knowledgeable of:

- The HACCP principles
- The technology or equipment used on processing lines
- The equipment preventative maintenance
- The practical aspects of product operations
- The flow of processes
- The sanitation techniques
- The applied aspects of product safety hazards as they relate to the elements identified in the company’s Gluten-Free Management System

Designated employees involved in the delivery of procedures developed in response to the requirements of the pre-requisite programs, CCP’s, process controls and reassessment activities must, at a minimum, be knowledgeable of their roles and responsibilities within the company’s Gluten-Free Management System.

It is important to note that the ultimate responsibility for achieving conformity under the Gluten-Free Certification Program resides with the facility operator and their employees. They cannot rely solely on the expertise of external consultants.

2.2.5 Gluten-Free Management System performance reporting

A documented procedure shall be established which defines how the Gluten-Free Management System performance is communicated to the senior manager who has signed the letter of commitment (see section 2.2.1).

The procedure shall include as a minimum:

- The name or title of personnel responsible to communicate the Gluten-Free Management System performance and verification results.
- The frequency of communication.
- The method used to communicate the information.
- The method used to demonstrate to the GFCP Approved Auditor that the communication took place.

The main objectives of the communication process are to:

- Make the facility’s senior management aware of the overall Gluten-Free Management System performance within their facility.
- Convey the information required for senior management to provide support and supply resources to the Gluten-Free Management System Team to ensure issues are corrected.

2.2.6 Signing and dating the Gluten-Free Management System documentation

The first page of the pre-requisite programs, Gluten-Free Management System and process control(s) shall be signed and dated by the Gluten-Free Management System Team leader or senior management representative:

- upon initial implementation;
- upon any modification;
- at least annually, upon reassessment.
All pages of the pre-requisite programs, Gluten-Free Management System, process control(s) and supporting documentation linked to the Gluten-Free Management System (standard operating procedures, work instructions, etc.) shall be dated:

- upon initial implementation; and
- upon any modification.

The signature shall signify that the pre-requisite programs, Gluten-Free Management System, process control(s) and supporting documentation have been approved by the Gluten-Free Management System Team leader or senior management representative and will be implemented as specified.

The facility's Gluten-Free Management System Team leader or senior management representative may utilize a stamp in lieu of their signature. The stamp must have their actual signature and may also incorporate the date. Procedures must be in place to ensure control over access and use of the stamp(s).

### 2.2.7 Control of records

Records shall be maintained to provide evidence of conformity to requirements and evidence of the effective operation of the Gluten-Free Management System.

Records maintained on computers are acceptable provided the facility implements appropriate controls to ensure the integrity of the electronic data. Access to the electronic data bank and the electronic signature must be secure.

Unless otherwise specified in GFCP requirements, records shall be retained for at least two years or for the shelf life of the product, whichever is greater.

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### Section 3 - Gluten-Free Management System Documentation

The Gluten-Free Management System documentation shall include:

- Pre-requisite programs (see section 3.1);
- Gluten-Free Management System (see section 3.2);
- Validation documentation for critical control points (CCP) or control measures (see section 3.3);
- Gluten-Free Management System maintenance and reassessment procedures (see section 3.4).

### 3.1 Pre-requisite programs

Prior to developing Gluten-Free Management System, the facility shall develop and implement pre-requisite programs to assist in controlling the likelihood of introducing product safety hazards to the product through the work environment and operational practices.

The pre-requisite programs shall be documented, updated whenever there are changes associated with the pre-requisite programs and reassessed at least annually.

The pre-requisite program requirements outlined in this manual are generic in nature. Facilities must ensure that their pre-requisite programs reflect the current work environment and operational practices within their facility and comply with specific commodity policies, manuals, procedures and associated regulations.

A facility may develop their pre-requisite programs using a structure other than the one described in this section as long as the pre-requisite program requirements are covered as well as the monitoring, deviation and record keeping...
components.

There are seven (7) pre-requisite programs:

- Premises
- Transportation, Purchasing/Receiving/Shipping and Storage
- Equipment
- Personnel
- Sanitation and Pest Control
- Recall
- Gluten Control

Each pre-requisite program is divided into Elements, Sub-elements and Bullets which include the requirements.

- A - Program (e.g., Premises)
- A.2 - Element (e.g., Building)
- A.2.2 - Sub-element (e.g., Lighting)
- A.2.2.1 - Bullet (Lighting is appropriate such that the print on labels and packaging is readily legible)

Each facility must create a documented program that responds to each pre-requisite program bullet requirement (see section 3.1.1). The documented program shall include:

- Specific programs, procedures or policies as per pre-requisite program bullet requirements;
- Monitoring procedure (see section 3.1.2);
- Deviation procedure (see section 3.1.3).

The record keeping shall meet the requirements defined in 3.1.4.

The facility may have to develop more programs, standard operating procedures or tasks to meet applicable regulatory requirements and/or to facilitate the control of the pre-requisite program requirements in their facility. Any additional product safety related programs, procedures or tasks shall be referenced within the respective bullet.

Note: The individuals responsible for specific control measures within a pre-requisite program, monitoring and deviation procedures may be identified by a position title or the term designate. In this case, the facility must be able to demonstrate that individuals have received adequate training.

3.1.1 Pre-requisite programs requirements

The seven pre-requisite programs include the following elements and sub-elements:

(A) Premises (see section 3.1.1.1)

- A.1 Outside Property
  - A.1.1 Outside Property

- A.2 Building
  - A.2.1 Building Design, Construction and Maintenance
  - A.2.2 Lighting
  - A.2.3 Ventilation
  - A.2.4 Waste and Inedible/Product Waste Disposal

- A.3 Sanitary Facilities
(B) Transportation, Purchasing/Receiving/Shipping and Storage (see section 3.1.1.2)

- B.1 Transportation
  - B.1.1 Product Carriers

- B.2 Purchasing/Receiving/Shipping and Storage
  - B.2.1 Purchasing/Receiving/Shipping
  - B.2.2 Storage

(C) Equipment (see section 3.1.1.3)

- C.1 Equipment General
  - C.1.1 Design & Installation
  - C.1.2 Equipment Maintenance and Calibration

(D) Personnel (see section 3.1.1.4)

- D.1 Training
  - D.1.1 General Product Hygiene Training Program
  - D.1.2 Technical Training Program

- D.2 General Product Hygiene Program
  - D.2.1 General Product Hygiene Program

(E) Sanitation and Pest Control (see section 3.1.1.5)

- E.1 Sanitation
  - E.1.1 Sanitation Program

- E.2 Pest Control
  - E.2.1 Pest Control Program

(F) Recall (see section 3.1.1.6)

- F.1 Recall System
  - F.1.1 Recall Plan
  - F.1.2 Product coding and labeling

(G) Allergen and Gluten Control (see section 3.1.1.7)

- G.1 Allergen and Gluten Control Program
  - G.1.1 Allergen and Gluten Control Program

Each pre-requisite program sub-element is organized under the following headings:
• The requirements
• Rationale - The rationale explains why the requirement exists

As this document applies to all product commodity groups, there will inevitably be situations where some of the specific requirements are not applicable. The requirements indicate where such questions are likely to arise by using the phrases where necessary, where appropriate or where applicable. In deciding whether a requirement is necessary or appropriate, an assessment of the risk and the regulatory requirements must be made and the result of the assessment must be recorded.

3.1.1.1 (A) Premises

A.1 External

A.1.1 Outside Property

Requirements

A.1.1.1

The facility is located away from or protected against potential sources of external contaminants that may compromise the safety of product.

The surrounding/roadways are free of debris and refuse, adequately drained and maintained to minimize environmental hazards.

Rationale

• Outside sources of contamination (e.g., excessive dust, pest infestation, airborne microbial and chemical contaminants) can lead to source of exterior contamination that can enter a facility.

A.2 Building

A.2.1 Building Design, Construction and Maintenance

Requirements

A.2.1.1

The building is designed and constructed:

• to meet regulatory and Gluten-Free Certification Program requirements;
• so its access is secure;
• so the roof, air intakes, foundation, walls, doors and windows prevent leakage and entry of contaminants and pests;
• to effectively separate incompatible operations,*
• to provide hygienic operations by means of a regulated flow from point of entry to the premises to the final product,*
• to effectively prevent cross-contamination due to employee traffic pattern, product flow and equipment,*
• so living quarters and areas where animals are kept are separated from and do not open directly into product processing or packaging areas;
• so incoming materials (food, non-food, packaging) are received in an area separate from product processing areas;
• so washrooms, lunchrooms and change rooms are separated from and do not open directly into product processing areas;
• so separate and adequate facilities are provided for:
  - the storage of waste and inedible products,*
  - the cleaning and sanitizing of waste/inedible equipment,*
  - the cleaning of equipment;*
• to prevent cross-connection between:
  - the effluent of human wastes and production drainage wastes in the facilities,
  - potable water lines and non-potable water supply systems;
    ▪ non-potable re-circulated/reused/recycled water has a separate distribution system which is readily identifiable in the facility.
• so the sewage and the waste effluent system do not pass directly over or through production unless they are controlled to prevent contamination;
• so drainage and sewage systems are equipped with functional traps and vents;
• so floors permit liquids to drain to trapped outlets;
• so floors, walls, doors, windows, ceilings, overheads and other structures in rooms or areas where product is manufactured, stored, packaged, received or shipped are cleanable, prevent contamination, prohibit deterioration, are suitable for the activities in each area and are free of any noxious constituents.**

* If the building is not designed to effectively separate incompatible operations and/or to prevent cross-contamination, operational procedures to control cross-contamination must be defined in the General Product Hygiene Program D.2.1.1. and/or the Sanitation Program E.1.1.1.

A.2.1.2

The building is maintained so:

• the roof, air intakes, foundation, walls, doors and windows prevent leakage and entry of contaminants and pests;
• the drainage and sewage systems prevent backflow and pooling liquids on floors;
• floors, walls, ceilings, overheads, doors, windows, stairs, elevators and other structures exhibit no evidence of degradation that would cause contamination and are cleanable.

Rationale

• Screens on windows, doors that are tight, a roof that does not leak and air intakes located away from potential contaminants are examples of good conditions which will minimize the potential for hazards such as rodents, pests, insects, non-potable water and the like entering the facility and compromising activities.
• Operational flows such as employee entry to the facility and flow to work rooms, ingredient/product flows and/or adequate separation or control between incompatible operations will prevent microbiological, chemical or physical contamination of the product.
• The absence of cross-connections between the sewage system and other waste systems will facilitate sanitary operations, ensure segregation of waste and prevent potential for contamination.
• Adequate drainage and/or an adequate waste disposal system will prevent cross-contamination of product, ingredients, packaging material, product contact surfaces or the potable water supply (e.g., drain back-ups leading to flooding).
• The presence of mechanisms to prevent backflow (e.g., trapping, venting) will prevent sewer gases, pests, microorganisms or other contaminants from entering the facility through the plumbing system.
• Floors that are designed to permit liquids to drain to trapped outlets will prevent water pooling or stagnant water on floors during operation.
• Some materials have the potential to cause biological, chemical or physical hazards. These materials should not be used in the construction of the facility's internal fittings where products are manufactured.
• Structures and materials that can be effectively cleaned will minimize the development of unsanitary conditions (e.g., presence of bacteria, mould).
• Materials that are durable or suitable for the environment or activities in the area will minimize unsuitable conditions (e.g., flaking or peeling rust or paint or loose materials).
• Ceilings and overhead structures that are well designed will minimize the build-up of dirt, condensation and the shedding of particles.
• Windows that are sealed or equipped with close-fitting screens and doors that are tight fitting will prevent entry of contaminants and pests.
• Windows constructed of, or protected with, unbreakable materials will prevent foreign material contamination of product, ingredients, packaging materials and product contact surfaces.

A.2.2 Lighting

Requirements

A.2.2.1

Lighting is appropriate such that the print and other marking on labels and packaging are readily legible.

A.2.2.2

Light bulbs and fixtures located in areas where there is exposed product or packaging materials are of a safety type or are protected to prevent contamination of product in case of breakage.

Rationale

• Lighting levels or quality could lead to misidentification of information on labels or packaging which could lead to contamination of product.
• If lighting levels are inadequate to perform the required tasks (including but not limited to inspection to determine product disposition, inspections during processing, inspections post-sanitation to ensure cleanliness and/or inspections in storage areas, as well as lighting levels that are adequate for the maintenance of equipment), this may prevent an employee from identifying the potential for or presence of biological, chemical or physical contamination.
• If a light bulb or lighting fixture breaks over exposed product, ingredients, packaging materials or product contact surfaces, then a physical foreign material hazard can occur.

A.2.3 Ventilation

Requirements

A.2.3.1

Ventilation provides sufficient air exchanges to prevent unacceptable accumulations of steam, condensation or dust and to remove contaminated air. Filters are cleaned or replaced as appropriate.

A.2.3.2
Ventilation systems ensure that air flows from the least contaminated areas to the most contaminated areas.

A.2.3.3

Where required, ambient air, compressed air or gases utilized in processing equipment that contact product or packaging are appropriately sourced and treated to minimize contamination of product and packaging.

Rationale

- Adequate ventilation minimizes airborne contamination of product (e.g., from aerosols or condensation droplets).
- The flow of contaminated air through a facility can be a source of bacterial contaminants for microbiologically sensitive product processing areas (e.g., Ready-to-Eat processing rooms and aseptic rooms) or gluten.
- The correct location of air intakes, the correct size of filters, filter cleanliness and the use of food grade gases all contribute to the prevention of airborne contamination.

A.2.4 Waste and Inedible/Food Waste Disposal

Waste is defined as unwanted materials left over from the manufacturing processes. This includes but is not limited to garbage, discarded packaging, broken pallets, discarded construction materials etc.

Inedible product or product waste is defined as any product that is not considered suitable for human consumption as defined in applicable legislation.

Requirements

A.2.4.1

The facility has and implements documented procedures to control the hazards associated with waste and inedible/food waste products. The procedures shall include but are not limited to:

- An identification system for utensils and containers used for collection and holding of waste and inedible/food waste materials;
- The frequency of removal of waste during operations;
- If applicable, the frequency of removal of inedible/food waste products during operations;
- If applicable, procedures for storage of waste and inedible/food waste products;
- If applicable (see regulatory requirement for the commodity), a denaturing protocol, including methods and chemical(s) used for denaturing;
- The frequency of removal of waste from the facility;
- If applicable, the frequency of removal of inedible/food waste product from the facility;
- Procedures for maintenance of waste/inedible/food waste equipment (Equipment must be leak proof and where appropriate, covered).

Rationale

- Clearly identified containers and utensils used for waste and inedible materials will prevent container or utensils misuse and cross-contamination of edible products
- Effective procedures will prevent the accumulation of waste, inedible or waste products and the potential contamination of product handling areas, and will minimize the attraction of pests and prevent objectionable odours.
A.3 Sanitary Facilities

A.3.1 Employees Facilities

Requirements

A.3.1.1

Washrooms have hot and cold or warm potable running water, soap dispensers, soap, sanitary hand drying equipment or supplies and cleanable waste receptacles. Hand washing notices are posted in appropriate areas.

A.3.1.2
As required, washrooms, lunchrooms and change rooms are provided with adequate floor drainage and ventilation. They are maintained in a manner to prevent contamination.

Rationale

- Adequate washroom, change room and lunchroom facilities will ensure that an appropriate degree of personal hygiene is maintained to protect the safety of product.
- Providing an acceptable area for employees to change into work clothes will prevent exterior contaminants from entering the processing areas.
- Providing adequate lunch room facilities will discourage employees from eating and drinking in production areas which can lead to contamination of product.

A.3.2 Hand-washing Stations and Sanitizing Installations

Requirements

A.3.2.1

Where required or appropriate, areas of the facility are provided with an adequate number of conveniently located hands free hand-washing stations with trapped waste pipes to drains.

Hand-washing stations are properly maintained and are provided with hot and cold or warm potable running water, soap dispensers, soap, sanitary hand drying equipment or supplies and cleanable waste receptacles. Hand-washing notices are posted in appropriate areas.

A.3.2.2

Where required/appropriate, areas of the facility are provided with sanitizing installations, such as:

- Sanitizing installations for hands
- Sanitizing installations for boots
- Sanitizer for operational equipment

Sanitizing installations are properly maintained and are provided with potable water at temperatures and, where applicable, chemical concentrations appropriate for their intended use.

Rationale

- Personnel are a major source of contaminant.
• If there are enough hand-washing stations and they are located in areas that are easy to access, personnel are more likely to wash their hands.
• Sanitizing stations are used to control the potential for cross-contamination from operational equipment and employees.
• Hand-washing stations and sanitizing installation can become a source of contaminants if they are not properly maintained.

A.4 Water/Ice/Steam Quality, Protection and Supply

A.4.1 Water/Ice/Steam Quality, Protection and Supply

Requirements

A.4.1.1

The facility has and implements documented water safety procedures to ensure that water and ice meet the potability requirements of the appropriate regulatory authority.

The water safety procedures shall include but are not limited to:

• Name or title of personnel responsible for the implementation of the water safety procedures;
• Identification of the source of water supply (municipality, private well(s), storage tank(s), etc.);
• Water sampling and testing schedule(s);
• Identification of the sampling site(s);
• Water and ice sampling procedures;
• Description of testing activities to be performed;
• Water potability criteria;
• Documentation requirements (records should include the water source(s), sampling site(s), analytical results, analyst and date of sample(s);
• Deviation procedures when water testing results indicate water potability criteria have not been met;
• Deviation procedures to be applied at the facility in instances where the municipality identifies a failure with the water system;
• Record(s) to be kept.

A.4.1.2

Where applicable, the facility has and implements documented water treatment procedures to ensure that:

• boiler feed water treatment or any chemically treated water (e.g., corrosion inhibitors, water conditioning and chlorination) that has direct product impact or is used on product contact surfaces meets the appropriate regulatory requirement and is potable;
• water mixed with chemical and applied on product to reduce the microbial load meets the acceptable chemical concentration for the intended purpose;
• re-circulated water for reuse meets the appropriate regulatory requirement.

The water treatment procedures shall include but are not limited to:

• Name or title of personnel responsible for the implementation of the water treatment procedures;
• Identification of water treatment activities to be performed;
• Water treatment method/frequency;
• Chemicals used;
• Proper handling and application of water treatment chemicals;
• Acceptable chemical concentrations;
• If applicable, description of any automatic warning control;
• Testing procedure, including testing frequency, to ensure proper concentration is consistently met;
• Documentation requirements (records should include method of treatment, sample site, analytical result, analyst and date);
• Deviation procedure when the criteria have not been met;
• Record(s) to be kept.

A.4.1.3
Where required, hoses, taps or other similar sources of possible contamination are designed to prevent backflow or back siphonage.

A.4.1.4
Where filters are used they are kept effective and maintained in a sanitary manner.

A.4.1.5
The volume, temperature and pressure of the potable water/steam are adequate for all operational and cleanup demands.

A.4.1.6
Where it is necessary to store water or ice, storage facilities are adequately designed, constructed, and maintained to prevent contamination.

Rationale
• Water, ice and steam can be a source of biological or chemical contaminants.
• Since water, ice and steam can be used for a variety of purposes (e.g., sanitation, hand washing, as an ingredient or processing aid), it is important to perform water sampling and testing to confirm potability.
• Collecting water samples from different outlet(s) for each test will ensure that the facility's water distribution system functions properly and is not a potential source of water contamination.
• Treated water can be a source of contaminants if the chemical treatment or treatment process is incorrectly performed and/or monitored.
• An adequate supply of potable water with appropriate facilities for its storage and distribution will prevent contamination of water and ensure the safety of product.
• If water and steam are not supplied at the necessary volume, pressure and temperature, the ability to properly complete certain activities can be compromised (e.g., hand washing, sanitation, product rinsing).

3.1.1.2 (B) Transportation, Purchasing/Receiving/Shipping and Storage

B.1 Transportation

B.1.1 Product Carriers

Requirements

B.1.1.1
Carriers used for transport of product:

- are designed, constructed, maintained and cleaned to prevent contamination, damage and deterioration of the product;
- are equipped, where applicable, to maintain products in a refrigerated or frozen state;
- are not being used for the transport of any material or substance that might adulterate the product.

B.1.1.2

Carriers are loaded, arranged and unloaded in a manner that:

- prevents outside contaminants from entering the facility;
- prevents damage and contamination of the finished product, ingredients and incoming materials that come in contact with the product or are used in preparing the product.

Rationale

- Conveyance vehicles or containers that are not properly constructed, maintained or cleaned can lead to a number of hazards including:
  - Physical contaminants from dust and foreign material;
  - Chemical contaminants from unsuitable surfaces or trace chemicals from previous loads;
  - Microbiological contaminants from previous loads.
- Adequate temperature control during transportation will minimize microbial growth, toxin formation and spoilage of the product.
- Transporting products and loads of non-compatible materials in one vehicle or container can lead to contamination of the product. A risk assessment should be performed to ensure product safety if this situation occurs.
- Carriers that are properly sealed to the building when loading or unloading will prevent outside contaminants/pests from entering the facility.
- Proper handling of incoming and outgoing material will prevent damage and contamination of the product and materials.

When loads are not properly handled, loaded and unloaded, contamination can occur from a variety of sources. For example:

- Forklifts can puncture holes in product containers leading to the introduction of microorganisms or physical contaminants;
- Incompatible products (e.g., non-food chemical product versus food product) can cross-contaminate each other leading to the introduction of chemical contamination;
- Temperature abuse from prolonged loading and unloading times can lead to the growth of microorganisms.

B.2 Purchasing/Receiving/Shipping and Storage

B.2.1 Purchasing/Receiving/Shipping

Requirements

B.2.1.1

The facility has and implements documented purchasing procedures to ensure that:
• Ingredients are ordered from suppliers/sources approved by the facility;
• The required information on ingredients is maintained on file (e.g., specifications, letters of guarantee, certificate of analysis);
• Construction materials, packaging materials and non-food chemical products conform to the requirements or guidelines issued by the applicable national, regulatory competent authority (e.g. US FDA Generally Recognized as Safe – GRAS)

B.2.1.2

Returned, defective or suspect product is clearly identified and isolated in a designated storage area, where it is assessed to determine the appropriate disposition.

B.2.1.3

Only approved ingredients and materials are received into the facility.

Incoming ingredients are assessed at receiving, where possible, to ensure that the purchasing specifications have been met.*

* Where organoleptic inspections are not effective as a means of confirming material acceptability for these materials, certificate of analysis may be used as a means to verify the commitment made by the suppliers.

B.2.1.4

All product safety specifications or requirements of the finished product have been met prior to shipping to retail/the customer. (e.g., temperature, certificate of analysis)

Finished product is adequately protected against intentional or unintentional contamination and deterioration prior to shipping.

Rationale

• Prevention of product, ingredient and packaging material contamination begins with control of incoming materials, including live animals.
• Inadequate incoming material controls can result in product contamination, inadequate processing or misrepresentation of the product.
• Packaging materials shall not impart any undesirable substance to the product, either biologically, chemically or physically and shall protect the product sufficiently to prevent contamination.
• Returned product left the control of the facility and may have been subjected to improper handling causing contamination or deterioration of the product.
• Control of returned products will prevent the contamination of other products.
• Controls prior to shipping will demonstrate that the finished product met all specifications prior to shipping.

B.2.2 Storage

Requirements

B.2.2.1

Temperatures of storage areas, processing areas, coolers and freezers meet regulated and/or acceptable temperatures.
B.2.2.2

Ingredients, finished products and packaging materials are handled and stored in a manner to prevent damage, deterioration and contamination.

Where applicable, ingredients and finished products are prepared in a manner to prevent time and temperature abuse associated with product safety or shelf life.

Where appropriate, rotation is controlled to prevent deterioration.

B.2.2.3

Non-food chemicals are received and stored in a dry, adequately ventilated area which is designed such that there is no possibility for cross-contamination of product, packaging materials or product contact surfaces.

When required for ongoing use in product handling areas, non-food chemicals are stored in a manner that prevents contamination of product, product contact surfaces or packaging material.

Non-food chemicals are mixed in clean, correctly labeled containers and dispensed and handled only by authorized and properly trained personnel.

Rationale

• Storing of products in an appropriately controlled environment will prevent contamination and deterioration of products.
• The protection of ingredients, product containers and packaging materials during storage will prevent contamination from micro-organisms, chemicals and foreign material (e.g., dust, insects, wood chips).
• Ingredients and finished products that are not properly rotated can reach their expiry date increasing the risk for the consumer.
• If chemicals are stored securely and separately from product, ingredients, packaging materials and product contact surfaces, contamination (e.g. spillage, accidental use or leakage) will be prevented.

3.1.1.3 (C) Equipment

C.1 Equipment General

C.1.1 Design & Installation

Requirements

C.1.1.1

Equipment is designed, constructed and installed to ensure that:

• it meets any government regulatory and program requirements;
• it is capable of delivering the requirements of the process and the sanitation program;
• it is accessible for cleaning, sanitizing, maintenance and inspection and is easily disassembled for those purposes;
• contamination of the product and product contact surfaces is prevented during operations;
• it permits proper drainage and where appropriate, it is connected directly to drains;
• it is smooth, non-corrosive, non-absorbent, non-toxic, free from pitting, cracks and crevices where there are product contact surfaces;
• it is, where necessary, exhausted to the outside to prevent condensation.

Utensils are constructed of non-toxic materials, do not present a foreign material hazard that could contaminate the product, and are easy to clean and sanitize.

Rationale

• Well-constructed and maintained equipment will minimize the potential for biological, chemical and physical hazards.
• Pits, cracks and crevices can provide areas for residues to accumulate and microorganisms to grow.
• Product residues that accumulate can contain allergenic components, gluten or microorganisms that can cause cross-contamination.
• Poor installation can result in parts or areas that cannot be properly cleaned, sanitized and inspected.
• Equipment that cannot be adequately inspected can result in hazards not being detected.
• Equipment product contact surfaces that are not suitable for the activities being performed can impart hazards to the products.
• Equipment used for cleaning and sanitizing that is capable of delivering the requirements of the sanitation program will facilitate a sanitary environment. (e.g., temperature indicators, racks, reels, hoses, CIP system).

C.1.2 Equipment Maintenance and Calibration

Requirements

C.1.2.1

The facility has and implements a documented Preventative Equipment Maintenance Program which includes but is not limited to:

• A list of equipment that may impact on product safety requiring regular maintenance;
• A preventative maintenance schedule or frequency of preventative maintenance activities;
• The maintenance procedures to perform for each preventative maintenance task;
• Records to be kept to demonstrate that the preventative maintenance tasks have been completed.

Note: The maintenance procedures are based on the equipment manufacturer's manual or equivalent, or are based on operating conditions that could affect the condition of the equipment.

C.1.2.2

The facility has and implements a documented Equipment Calibration Program which includes but is not limited to:

• A list of equipment monitoring and controlling devices that may impact on product safety requiring regular calibration;
• A calibration schedule or frequency of calibration activities;
• The calibration procedures to perform for each calibration task;
• Records to be kept to demonstrate that the calibration tasks have been completed.

Rationale

• An effective maintenance program will ensure that equipment performs consistently as intended and prevents contamination of product, ingredients or packaging materials.
• Controlling devices must be accurate because they are used in critical processes which impact on product safety.

3.1.1.4  (D) Personnel

D.1 Training

D.1.1 General Product Hygiene Training

Requirements

D.1.1.1

The facility has and implements a documented general product hygiene training program which includes but is not limited to:

• The facility’s general product hygiene program (see D.2.1.1);
• A list of employee positions who must receive the training;
  - All product handling employees and other employees that may work in product handling areas (e.g., maintenance staff, quality assurance (QA) staff, supervisors, etc.)
• The frequency of training;
  - The training is delivered at the start of employment, whenever changes are made to the program and reinforced at appropriate intervals
• Records to be kept to prove completion of personnel training.

Rationale

• Recognized facility personnel play a major role in the production of safe product.
• Proper training reduces the risk of biological, chemical and physical contamination.
• Training increases awareness of potential hazards and the responsibilities that personnel have to minimize contamination risks.

D.1.2 Technical Training

Requirements

D.1.2.1

The facility has and implements a documented Technical Training Program which includes but is not limited to:

• The pre-requisite programs;
• The CCP(s) or control measure, if applicable;
• The process control(s), if applicable;
• Any additional external technical training that is necessary to ensure current knowledge of equipment and process technology (e.g., licenses/certification required to operate equipment—HTST operator’s certification / retort operator certification);
• A list of employee positions who must receive the training;
  - Designated employees involved in the delivery of procedures developed in response to the pre-requisite programs requirements, CCP’s, and process controls
The frequency of training:
- The training is delivered before the beginning of assignment and reinforced whenever changes are made and at appropriate intervals
- A method to confirm that the training has been effectively understood;
- Records to be kept to prove completion of personnel training.

Rationale
- Training is delivered to ensure that personnel understand and are competent in procedures which they are designated to perform.
- Proper training reduces the risk of biological, chemical and physical contamination of product.

D.2 General Product Hygiene Program

D.2.1 General Product Hygiene Program

Requirements

D.2.1.1

The facility has and implements a documented General Product Hygiene Program which includes, but is not limited to:

- Good Manufacturing and Personnel Hygiene Practices:
  - Methods for hand washing/sanitizing;
  - Correct use of protective clothing, hair coverings, gloves, footwear;
  - Prohibited practices at the facility;
  - Hygienic handling of product;
  - Correct use of utensils and equipment;
  - Storage of personal effects to prevent cross-contamination;
  - Where required, restricted access to areas of the facilities by specific employees to prevent cross-contamination;
  - When required, procedures to prevent contamination due to the process flow, employee flow, product flow, equipment or incompatible operations;
  - When required, procedures to prevent cross-contamination during production. For example:
    - glass control and breakage procedures
    - procedures to follow when:
      - product falls on the floor,
      - product is exposed to dripping condensation;
  - Procedures for visitors and contractors during production including:
    - restricted access,
    - hygienic practices;

- Personnel Health Status:
  - the program must clearly state that personnel must advise management when known to be suffering from a disease likely to be transmitted through product;
  - no person is permitted to work in a product handling area when he or she is known to be suffering or a carrier of a disease likely to be transmitted through product;
  - employees having open cuts or wounds should not handle product or product contact surfaces unless the injury is completely protected by a secure waterproof covering.
Rationale

- Employees play a major role in the production of safe product
- Employees, visitors or contractors that do not follow the facility's rules can cause contamination of product.
- Personnel suffering from disease through product (e.g. Salmonella, Hepatitis A) can contaminate the product being produced. The contaminated products can transmit the disease to the consumer.
- Developing and enforcing a product hygiene program will reduce potential hazards and minimize contamination risks.

3.1.1.5  (E) Sanitation and Pest Control

E.1 Sanitation

E.1.1 Sanitation Program

Requirements

E.1.1.1

The facility has and implements a documented Sanitation Program which includes but is not limited to:

- The sanitation schedule/frequency for all equipment, and for all rooms that, if not kept in a clean/sanitary condition, would have a negative effect on product safety within the facility including utensils, waste and inedible/food waste equipment and facilities, work gear etc. that, if not kept in a clean/sanitary condition, would have a negative effect on product safety;
- Cleaning and sanitizing procedures including:
  - Details and specifics describing the method and procedures for equipment and room cleaning and sanitizing,
  - The chemicals required,
  - The chemical concentration level required,
  - Proper handling and application of chemicals (duration of application, etc)
  - The chemical solution temperatures, where applicable,
  - Equipment disassembly and assembly instructions,
  - Methods to prevent cross-contamination, where necessary;
- Housekeeping and sanitation procedures required during operations;
- Pre-operational inspection procedures;
- Environmental sampling procedures, if any;
- Corrective actions to be taken for non-compliant situations observed during pre-operational inspection activities and unsatisfactory environmental testing results;
- Records to be kept.

Rationale

- Improper or inadequate sanitation activities can lead to contamination of product, ingredients, packaging materials and product contact surfaces.
- The use of improper chemical concentrations and/or improper chemical application or rinsing procedures can lead to both chemical contamination (e.g., chemical residue due to poor rinsing, no-rinse chemicals in excess of approved concentration) and biological contamination (e.g., bacteria not effectively removed from product contact surfaces).
- Chemical contamination can also be caused by allergen or gluten that are not effectively removed from product contact surfaces.
Chemical or biological contamination can be caused by cross-contamination from cleaning activities during operation.

E.2 Pest Control

E.2.1 Pest Control Program

Requirements

E.2.1.1

The facility has and implements a documented Pest Control Program which includes but is not limited to:

- Where applicable, the name of the pest control company or the name of the person contracted for the pest control program;
- The name of the person at the facility assigned responsibility for pest control;
- A schedule or frequency of pest control activities;
- Pest control procedures for the exterior and interior of the facility including:
  - The pest control activities to be performed;
  - The chemicals required for the effective implementation of the pest control program;
  - The methods for proper handling and application of pest control chemicals;
  - The type and location of pest control devices;
  - Corrective actions to be taken for non-compliant situations observed during pest control activities,
  - Records to be kept.

Rationale

Pests (e.g., insects, rodents and birds) can contaminate product, ingredients, packaging materials and product contact surfaces. Pests in or around a facility can lead to contamination from dropping, larvae and dead insects or animals.

3.1.1.6 (F) Recall

F.1 Recall System

F.1.1 Recall Plan

The Gluten-Free Certification Program will use the information described and/or required by the national, regulatory competent authority to assess completeness of the facility written recall plan.

Requirements

F.1.1.1

The facility has and implements a documented Recall Plan which includes but is not limited to:

- Names of employees on the Recall Management Team including position, contact phone numbers and responsibilities.
- Notification/Complaint File including:
  - recording of the initial notification/complaint information;
  - investigation of the notification/complaint and a record of the findings;
- action taken based on the investigation findings;
- record of action taken.

- Recall Contact List – national, regulatory competent authority and ACG notification including:
  - title of the national, regulatory competent authority and ACG contacts;
  - contact telephone numbers;
  - contact fax numbers.
  - other means of communication
- Methods to trace product.
  - Maintain product identification throughout the process until final packaging, including:
    - raw ingredient tracing;
    - premixing of ingredients ahead of use;
    - re-work.
  - Coding system documentation.
- Method(s) to record the amount of each lot code of each product produced.
- Distribution records and distribution record system for each lot of product including:
  - name of the account and address;
  - type of account (e.g., manufacturer, distributor, retailer);
  - product name and lot code;
  - who to contact at the account;
  - telephone number and other contact numbers consistent with the documented method of contact during the recall (e.g. fax number, e-mail address);
  - amount of product shipped to each account.
- Procedure(s) for developing, producing and maintaining recalled product records.
- Step by step recall procedures which will be followed during a recall, including:
  - assemble the Recall Management Team;
  - notify the national, regulatory competent authority and ACG for any product deemed to be GFCP Certified;
  - identify all products to be recalled;
  - detain and segregate all products to be recalled which are in the facility's control;
  - prepare the press release, if required;
  - prepare the distribution list;
  - prepare and distribute the notice of recall;
  - verify the effectiveness of the recall;
  - control the recalled product(s);
  - disposition of the recalled product(s);
  - identify and correct the cause of the recall if the problem occurred at the facility.
- Methods to assess the effectiveness of the facility's recall notification.
- Procedures for testing the recall plan (mock recall exercise).
- Records to be kept in case of recalls.

**Rationale**

- Product recalls can be triggered by a number of hazards within or external to a facility.
- Quickly re-gaining control of implicated lots of product is crucial in preventing the risk of hazard to consumers.

**F.1.2 Product Coding and Labeling**

**Requirements**
F.1.2.1

The facility has and implements documented operational procedures to ensure that:

- finished products are correctly and legibly coded;
- the finished product label information accurately represents the product name and the composition of the product on which the label is affixed.

The procedure to prevent incorrect labeling/coding shall include but is not limited to:

- the names or title of personnel responsible for particular task;
- frequency of activity;
- description of the task to be performed;
- corrective actions to be taken when product is mislabeled or miscoded;
- operational records to be kept.

Rationale

- Product must be correctly labeled to enable the next person in the product chain to handle, display, store, and use the product safely.
- Incorrectly coded expiry dates can result in consumers storing the product past the intended shelf life, leading to potential product safety hazards.
- Incorrect labeling or coding can make product recall difficult or unfeasible if a hazard is associated with the mislabeled or miscoded product.

3.1.1.7 (G) Allergen and Gluten Control

For hypersensitive individuals, certain products and their derivatives can cause allergic reactions or develop into Celiac Disease. Product allergy is an abnormal immune response whereas gluten causes and auto-immune response to specific proteins found in product. These reactions cannot occur in the absence of proteins. These proteins (antigens) are capable of stimulating the production of antibodies in the body, thereby, triggering allergic reactions or auto-immune responses like celiac disease. There is no cure for product allergies or celiac disease and the only way for an afflicted individual to protect themselves is strict avoidance of the offending component.

This section outlines the requirements that a Gluten Control Program must meet to control the use of ingredients identified as allergen, specifically gluten in a facility, as well as to prevent or identify the presence of undeclared gluten ingredients in finished products.

Unlike microbial hazards, there is no lethality or post processing step that will reduce or eliminate the presence of undeclared gluten in products. Control is dependent on prevention throughout the process as well as appropriate product labelling to ensure full disclosure of a product’s contents. The list of the priority product allergens is available on the USFDA website. The main focus of the Gluten-Free Certification Program is the management of gluten such that the finished product conforms to Division 24 Special Dietary Foods.

Manufacturers exporting outside of USA should be aware that the list of priority allergens in other countries may be different from those listed in USA.
G.1 Allergen and Gluten Control Program

G.1.1 Allergen and Gluten Control Program

**NOTE 1:** Each of the requirements outlined below may not be applicable to every facility. In deciding whether a requirement is necessary or appropriate, a facility must conduct a risk assessment and the result of the assessment must be recorded.

**NOTE 2:** Reference to existing pre-requisite programs, CCP’s or other control measures that cover the requirements mentioned in this section is acceptable. The purpose of the Gluten Control Program is to gather all of the gluten controls in one location in the Gluten-Free Management System.

Requirements

**G.1.1.1**

Where applicable, procedures and/or policies are developed and implemented to ensure proper 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.

**G.1.1.2**

Where applicable, procedures and/or policies related to purchasing of ingredients are developed and implemented to ensure proper control and identification of gluten for incoming ingredients. This must include a minimum of:

- identification of any gluten not allowed in a facility if such a policy is in place;
- a list of approved suppliers and ingredients;
- supplier specification for each ingredient or ingredient blend clearly listing each ingredient and, where applicable, components of ingredients;
- documentation indicating that the supplier will:
  - meet the facility's specifications;
  - notify the facility when a change is made to their ingredient blend formula which adds or eliminates an allergen or gluten.

**G.1.1.3**

Where applicable, the procedures and/or policies are developed and implemented to ensure proper control of new or modified labels. This must include a minimum of:

- a label approval process including steps to be followed in case of re-approval of product labels resulting from modifications to existing product formulations;
- the communication links among all the steps in the chain of production once a new label, or changes to a new label, have been approved.

**G.1.1.4**
Where applicable, procedures and/or policies related to receiving of ingredients and externally printed labels are developed and implemented to ensure that:

- only approved ingredients from approved suppliers/sources are received;
- the labels of approved ingredients received match the facility's finished product list of ingredients and components of ingredients;
- externally printed labels meet the specifications.

G.1.1.5

Where applicable, procedures associated with Weighing/Blending/Mixing/Formulation are developed and implemented to ensure that the correct ingredient is added to the correct product as indicated in the formula. This must include a minimum of:

- the names or titles of personnel responsible for these particular tasks;
- methods or instructions for the task(s) to be performed;
- corrective actions to be taken when deviant situations occur during any of these steps;
- operational records to be kept.

G.1.1.6

Where applicable, procedures and/or policies related to the use of rework are developed and implemented to ensure that the rework formulation ingredients and the product formulation ingredients match, specifically as it applies to allergen or gluten containing ingredients.

G.1.1.7

Where applicable, procedures related to labeling of finished product are 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. This must include a minimum of:

- the names or title of personnel responsible for particular tasks;
- frequency of activity;
- methods or instructions for the task(s) to be performed;
- corrective actions to be taken when product is mislabeled;
- operational records to be kept.

G.1.1.8

Where applicable, the procedures and/or policies for disposal of obsolete materials are developed and implemented to prevent their inadvertent use. Obsolete materials include:

- labels (refers to any pre-printed packaging that bears a list of ingredients);
- formula documents;
- ingredients and work in process.
G.1.1.9

Where applicable, the procedures and/or policies are developed and implemented to control cross-contamination of undeclared allergen or gluten sources in the products. Procedures include as a minimum, the management and control of:

- production scheduling if dedicated lines for allergen or gluten source are not available;
- traffic patterns of employees who handle allergen or gluten source and non-allergens or non-gluten;
- the traffic flow and handling of ingredients containing allergen or gluten source during receiving, storage, processing and packaging;
- dedicated or segregated storage of ingredients containing allergen or gluten source;
- the identification and sanitation of bulk containers housing allergen or gluten source or ingredients containing allergen or gluten source;
- dedicated utensils, equipment and areas used to handle allergen or gluten source;
- the handling and storage of rework product(s) containing allergen or gluten source ingredients;
- cleaning of equipment/product contact surfaces/areas during operations if dedicated lines/equipment/areas for allergen or gluten source are not available.

Rationale

- Consumers who have allergies and intolerances rely on accurate label information on products to avoid eating products that contain ingredients to which they may be sensitive or wish to avoid.
- If these products, or their derivatives, are undeclared or declared incorrectly on the label, or if inadvertent cross-contamination occurs during production, the results can be serious and sometimes fatal.

3.1.2 Monitoring procedures

Documented monitoring procedures shall be established for each pre-requisite program bullet and shall specify any tests, measurements or observations to assess whether:

- the programs, policies, standard operating procedures and tasks defined or referenced in the pre-requisite programs are effectively implemented;
- those standards are met.

The monitoring procedure shall at least include:

- Name or title of personnel responsible for the monitoring and evaluation of monitoring results;
- Monitoring frequency;
- The standard(s) to be met;
- Methods or instructions for testing, measurements or observations to be performed;
- Exact title of the record(s) used to document monitoring results;
- Record keeping instructions (see section 3.1.4).

The monitoring frequency must:

- be auditable/measurable (i.e., as required is not auditable);
- provide effective control to ensure the pre-requisite program requirements are consistently met; and
- be at a minimum of once per year.

Standards are criteria or specifications that can be judged or evaluated and that define the limit of acceptability associated with a pre-requisite program requirement. Criteria must be measurable. These may
either be quantitative (e.g. degrees) or qualitative (e.g. no holes in the carrier, product is stored off the floor). Criteria must be clearly described to be easily understood and uniformly applied by those responsible for monitoring.

There may be specific regulatory standards that apply to specific pre-requisite program requirements. The regulatory standards must be addressed in the Gluten-Free Management System. The facility may establish higher standards than the existing regulatory requirements.

To ensure validity of results, tests, methods and instructions must be described in enough detail to ensure consistency in delivery between different monitors.

3.1.3 Deviation procedures

Documented deviation procedures shall specify any planned or appropriate corrective actions to be taken when monitoring results demonstrate that:

• the programs, policies, standard operating procedures and tasks defined or referenced in the pre-requisite programs are not effectively implemented;
• the standards are not met.

The deviation procedure shall at least include:

• Name or title of personnel that have the responsibility and authority to take actions.
• Instructions on corrective actions to be taken.*
• Exact title of the record(s) used to describe the deviation and to document all actions taken in response to a deviation.
• Record keeping instructions (see section 3.1.4).

* The deviation procedure for pre-requisite programs shall at least instruct the responsible employees to perform and document the following activities:

• Describe the deviation and its cause.
• Take immediate actions to control affected or potentially affected product.**
• Implement corrective actions to restore control of the pre-requisite program requirement(s).
• Verify the effectiveness of corrective actions taken.
• Evaluate the need to implement additional measures to prevent reoccurrence of the deviation.***
• Verify effectiveness of preventative measures if taken.

** When product is affected or potentially affected, the individual with authority shall:

• Prevent the on-going production of non-compliant product;
• Control the non-compliant product that has been produced;
• Assess if other products are implicated in relation to the cause of the deviation;
• Perform an assessment of the affected product to determine if the product may be released (see section 3.2.7.3.1);
• Determine the disposition of non-compliant product (see section 3.2.7.3.2).

*** Preventative measures shall be applied when:

• Product is affected or potentially affected;
Repeated deviations are noted during monitoring activities which may indicate a trend toward a loss of control.

3.1.4 Record keeping

Records shall be kept to demonstrate the effective application of the pre-requisite programs and to facilitate official verifications by the GFCP Approved Auditor or other competent authority. Records shall be established to document:

- The monitoring results, including the recording of actual quantifiable values (e.g., temperature), when applicable;
- All information and actions taken in response to a deviation identified as a result of monitoring.

Records must be up-to-date, legible, accurate and properly filed.

Each monitoring record and/or action taken in response to a deviation shall be signed or initialed by the employee making the entry using a permanent ink pen or, when computer records are used, the record may be signed electronically. Monitoring records and/or action taken in response to a deviation shall be dated.

Deviations shall identify a target date for completion of preventative measures.

Any incorrect entry made to a record and subsequently changed shall be crossed out and initialed by the employee making the change.

3.2 Gluten-Free Management System

Facilities shall conduct a complete hazard analysis for all of their processes and products in order to identify and control all hazards effectively.

A Gluten-Free Management System is a written document designed in accordance with the following steps to ensure control of product safety hazards within a facility.

There are 12 steps to developing each Gluten-Free Management System. These steps are as follows:

1. Assemble the team
2. Describe the product and identify its intended use (e.g. gluten-free)
3. List product ingredients and incoming material
4. Construct a process flow diagram and confirm its accuracy
5. Construct a plant schematic and confirm its accuracy
6. Identify and analyze hazards (HACCP Principle 1)*
7. Determine critical control point(s) (CCP) and other control measures i.e. process control (PC) and pre-requisite programs (PP) (HACCP Principle 2)
8. Establish critical limits (HACCP Principle 3)
9. Establish monitoring procedures (HACCP Principle 4)
10. Establish deviation procedures (HACCP Principle 5)
11. Establish verification procedures (Principle 6)
12. Establish record keeping (HACCP Principle 7)

*Note: Mandatory for gluten as the hazard in non-dedicated gluten-free facilities which otherwise need documented PRP’s for gluten management
Steps 1 to 5 are preliminary steps to enable hazard analysis. Steps 6 to 12 incorporate the 7 principles of HACCP developed by the Codex Alimentarius Commission.

All relevant information needed to conduct the preliminary steps, the hazard analysis, and the facility of the critical control points and process controls shall be documented, updated whenever there are changes, and reassessed at least annually. The Gluten-Free Certification Program has created 10 specific forms that can be used for the documentation of a Gluten-Free Management System. If a facility uses forms other than those found in this manual, the content must be equivalent and provide sufficient detail.

The 10 Gluten-Free Management System forms are:

- Form 1: Product Description
- Form 2: List of Product Ingredients and Incoming Material
- Form 3: Process Flow Diagram
- Form 4: Plant Schematic
- Form 5: Biological Hazard Identification
- Form 6: Chemical Hazard Identification*
- Form 7: Physical Hazard Identification
- Form 8: Decision Tree - CCP and other Control Measures Determination (PP, PC)
- Form 9: Hazards Not Controlled by the facility
- Form 10: CCP and other Control Measures (PP, PC)

*Note: Mandatory for gluten as the hazard

The 11 blank template forms, including an example of an alternative form that will allow for the combination of Forms 5, 6, 7, 8 and 9 can be found in section 3.5.

In performing the step by step analysis above, the Gluten-Free Management Team may determine that several products share similar hazards, processing steps or equipment. In that case, the Gluten-Free Management Team may group these products or processes into one Gluten-Free Management System.

If a facility chooses to group dissimilar processes or products into one Gluten-Free Management System, they will be required to demonstrate to the GFCP Approved Auditor that the Gluten-Free Management System identifies and controls all potential hazards.

3.2.1 Describe product and identify its intended use (Form 1)

The description of finished products shall be documented in Form 1 or equivalent to the extent needed to conduct the hazard analysis, including information on the following, as appropriate:

- Process/product type name;
- Product name;
- Important product characteristics;
- Intended use;
- Packaging;
- Intended shelf life and storage conditions;
- Where the product will be sold;
- Labeling instructions relating to product safety (e.g. Gluten-Free Certification Program Trademark(s));
- Special distribution control.

The Gluten-Free Management Team shall identify regulatory product safety requirements related to the above.
3.2.1.1  Process/product type name

The generic or common name of the product family or process covered by the Gluten-Free Management System shall be documented in Form 1 or equivalent.

3.2.1.2  Product name

The brand name and/or common name of the individual products covered by the Gluten-Free Management System shall be documented in Form 1 or equivalent. Reference to a list of product names is acceptable.

3.2.1.3  Important product characteristics

The physical, chemical and biological characteristics of the product (such as pH, Aw, salt content, concentration of preservatives, etc.) that could affect product safety if not properly controlled shall be documented in Form 1 or equivalent.

3.2.1.4  Intended use

The intended use is based on the expected uses of the product by the end user (e.g., ready-to-eat product, ready-to-cook, for further processing).

The intended use shall be described in Form 1 or equivalent.

3.2.1.5  Packaging

All types of packaging to be used by the facility for the final product (e.g., drums, pails, cryovac bags, modified atmosphere, hermetically sealed) and their applicable size (e.g., consumer-size, bulk packs destined for further processing) shall be documented in Form 1 or equivalent to enable hazard analysis.

A reference to a list of types of packaging and applicable sizes is acceptable.

3.2.1.6  Intended shelf life and storage conditions

The intended shelf life of the product under normal marketing conditions at a given storage temperature and, where applicable, humidity shall be documented in Form 1 or equivalent to enable hazard analysis.

When establishing product shelf life, it is the responsibility of the manufacturer to ensure and to demonstrate that the safety of the product can be retained throughout the maximum period specified.

3.2.1.7  Where the product will be sold

The points of sale, target groups of users and, where appropriate, more specific groups of consumers shall be identified on Form 1 or equivalent for each product (e.g., retail, general population, celiac, gluten intolerant, infants, hospital). More specifically consumer groups known to be especially vulnerable to specific product safety hazards shall be considered.

3.2.1.8  Labeling instructions related to product safety

Any labeling instructions for handling, preparation and usage which have an impact of product safety shall be identified in Form 1 or equivalent (e.g., cooking and storage instructions, best before date).

3.2.1.9  Special distribution control
Special controls required during transportation and storage (e.g., temperature, humidity) shall be documented in Form 1 or equivalent.

3.2.2 List product ingredients and incoming materials (Form 2)

All ingredients, including composition of formulated ingredients (with reference to other documents if needed), additives, processing aids and incoming materials that come in contact with the product or are used in preparing the product shall be described in Form 2 or equivalent, to the extent needed to conduct the hazard analysis.

Particular care must be taken for additives, processing aids and ingredients (including second generation ingredients), that have received regulatory approval for specific products only.

3.2.3 Construct a process flow diagram and confirm its accuracy (Form 3)

Flow diagram(s) shall be prepared for the product(s) or process categories covered by the Gluten-Free Management System. Flow diagrams shall provide a basis for evaluating the possible occurrence or introduction of and/or increase in product safety hazards.

Flow diagrams shall be clear, accurate and sufficiently detailed. Flow diagrams shall, as appropriate, include:

- The sequence and interaction of all steps in the operation from receiving to final shipping;
- The introduction of ingredients and intermediate products into the process flow;
- The introduction of product for reworking.

The Gluten-Free Management Team shall verify the accuracy and completeness of the flow diagrams by on-site checking.

3.2.4 Construct a plant schematic and confirm its accuracy (Form 4)

A plant schematic shall be prepared for the products or process categories covered by the Gluten-Free Management System. Plant schematic provides a basis for evaluating potential areas of cross-contamination.

Plant schematic shall be clear, accurate and sufficiently detailed. Plant schematic shall at least include:

- The flows of raw products, ingredients and finished products.
- The flows of packaging materials.
- The employee traffic pattern throughout the facility including change rooms, washrooms and lunchrooms.
- The flows of the waste, inedible products and other non-food products that could cause cross-contamination.
- The hand/boot washing and sanitizing installations.

The GFCP Approved Auditor shall verify the accuracy and completeness of the plant schematic by on-site checking.

The overall evaluation of potential areas of cross-contamination at the facility should include any other plant schematic from any other Gluten-Free Management System(s).

3.2.5 Identify and analyze hazards (HACCP Principle 1) (Forms 5, 6, 7)

The hazard identification (Note: glutens source identification is mandatory) shall be based on:
• The information collected according to 3.2.1 to 3.2.4.
• Employees' knowledge and experience on practical aspects of the facility operations.
• Documented production issues such as files on production rework, returned products, product complaints and recalls.
• External information including reference texts, scientific publications, and government guides.

If biological (B), chemical (C) or physical (P) hazards associated with the ingredients and incoming materials are identified, the letters B, C or P shall be indicated in Form 2 or equivalent beside each corresponding ingredient or incoming material. The hazards shall be fully described in Forms 5, 6, 7 or equivalent.

If biological, chemical or physical hazards associated with the processing steps are identified, the letters B, C or P shall be indicated in Form 3 or equivalent beside each corresponding step. The hazards shall be fully described in Forms 5, 6, 7 or equivalent.

If biological, chemical or physical hazards associated with cross-contamination points are identified, the letters B, C or P shall be indicated in Form 4 or equivalent at the corresponding cross-contamination point. The hazards shall be fully described in Forms 5, 6, 7 or equivalent.

3.2.6 Determination of CCP and other Control Measures (HACCP Principle 2) (Form 8)

For each hazard identified, an analysis shall be conducted to determine:

• The likely occurrence of the hazard.
• The severity of possible adverse health effect associated with the hazard.
• If the identified hazard is controlled by pre-requisite programs.
• If the identified hazard is partially controlled by a process control.
• If the identified hazard is controlled at a CCP or a control measure.
• If the identified hazard is out of the facility's control.

The facility shall use Form 8 or equivalent to document the hazard analysis as well as the pre-requisite programs (PP), the process controls (PC) and the CCP or control measure selected to control the product safety hazards identified.

All PP(s), PC(s) and CCP(s) associated with the processing steps shall be indicated beside the corresponding step in Form 3 or equivalent.

Note: To facilitate verification by GFCP Approved Auditor, the Gluten-free Certification Program recommends facilities number the CCP or other control measures sequentially and identify the hazard(s) each controls i.e., B for biological, C for chemical, P for physical hazards. (e.g. CCP1-BCP, CCP2-B).

3.2.6.1 Using Form 8 - decision tree - CCP determination and other control measures (PP, PC)

Form 8 - Column 1

List each ingredient and incoming material, process step and cross-contamination point where a hazard has been identified. Use one line per hazard.

Form 8 - Column 2

Categorize (biological, chemical, physical) and fully describe each of the identified hazards. Where multiple hazards exist at one point, each hazard should be analyzed separately.
For each hazard, determine whether it is fully controlled by one or more pre-requisite programs. If the answer is yes, identify the pre-requisite program bullet(s) that provides full control over this hazard.

To assess whether the hazard is fully controlled by a pre-requisite program, the Gluten-Free Management Team must first review the documented written program(s) for the specific bullet(s). They must then conduct a record review and on-site observations to ensure that the policies and procedures in place provide effective control over the hazard identified in the Gluten-Free Management System. If the Gluten-Free Management Team determines that the hazard is not fully controlled by a pre-requisite program, proceed to Question 1.

**Form 8 - Question 1**

Q1. Could a control measure(s) be used by the facility at any process step?

Could a control measure occur at this step - or at any other process step - to control the hazard? Does the facility have or could they add a process step to control the hazard?

If the answer is yes, describe the control measure and proceed to Q2.

If the answer is no (a control measure cannot be implemented at a process step), identify how the hazard will be controlled before or after the manufacturing process on Form 9 or equivalent and proceed to the next identified hazard.

**Form 8 - Question 2**

Q2. Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level?

Question 2 refers to the probability and seriousness of the hazard. If there were no controls in place, how likely is this hazard to occur in excess of acceptable levels? *

* Acceptable level- The level at which the finished product will not cause harm to the consumer when it is prepared and/or consumed according to its intended use.

Conduct a hazard analysis based on all the information that the Gluten-Free Management Team has gathered.

If information gathered suggests that contamination with the identified hazard could increase to an unacceptable level and result in a health hazard, answer yes and proceed to Question 3. Identify the acceptable level of the product safety hazard in the finished product, wherever possible.

If contamination is not likely to occur, or is not known to affect the safety of the product, answer no and proceed to the next identified hazard. For further reference, the Gluten-Free Management Team must document the reasons for answering no.

**Form 8 - Question 3**

Q3. Is this process step specifically designed to prevent, eliminate or reduce the likely occurrence of the identified hazard to an acceptable level?

If the process step has been specifically designed to prevent, eliminate or reduce the likely occurrence of the hazard to an acceptable level, answer yes. Designate this process step as a CCP and identify it in the last column. If the answer is no, proceed to Question 4.
**Note:** Question 3 applies only to processing steps. For incoming materials, write not applicable (N/A) and proceed to Question 4.

**Form 8 - Question 4**

Q4. Will a subsequent step eliminate the identified hazard or reduce its likely occurrence to an acceptable level?

Answer no if no subsequent processing steps listed on the process flow diagram will eliminate or reduce the hazard to an acceptable level. Designate this process step a CCP and identify it in the last column and proceed to the next identified hazard. If the answer is yes, identify the subsequent step or steps that control the hazard. Then proceed to Question 5.

**Form 8 - Question 5**

Q5. Does this step provide partial control of the identified hazard?

If the answer is yes, this process step is a process control. Enter the process control number in the last column then proceed to the next identified hazard. If the answer is no, proceed to the next identified hazard.

3.2.6.2 **Hazards not controlled by the facility (Form 9)**

All hazards that affect the facility’s products shall be analyzed. Hazards that are out of the control of the facility, as well as a description of how the hazard is controlled before or after the production process shall be documented on Form 9 or equivalent.

3.2.7 **Critical control points and other control measures (Form 10)**

A CCP is a point or a step at which a control measure is applied and where it is essential to prevent or eliminate one or more product safety hazards or reduce them to an acceptable level.

Each CCP or control measure shall be documented in Form 10 or equivalent and shall include the following information:

- Hazard(s) to be controlled at the CCP and description of control measure(s);
- Critical limit(s) (see section 3.2.7.1).
- Monitoring procedure(s) (see section 3.2.7.2).
- Deviation procedures (see section 3.2.7.3).
- Verification procedure(s) (see section 3.2.7.4).

The record keeping shall meet the requirements defined in 3.2.7.5.

The CCP or musts in the pre-requisite programs shall be validated, updated whenever there are changes associated with the CCP, control measure or pre-requisite programs and reassessed at least annually.

**Note:** The individual(s) responsible for monitoring, deviation and verification procedures may be identified by a position title or the term designate. In this case, the facility must be able to demonstrate that individuals have received adequate training.

3.2.7.1 **Critical limits (HACCP Principle 3)**
Critical limits are criteria that separate acceptability from unacceptability. These parameters, if properly maintained, will confirm the safety of the product.

Critical limits shall be determined for the monitoring established for each CCP or control measure. One or more critical limits may be used to control the identified hazards.

Critical limits shall be established to ensure that the identified acceptable level of the product safety hazard in the finished product is not exceeded. Where government regulations exist, the critical limit, at a minimum, must meet those regulations.

Critical limits shall be measurable. Critical limits based on subjective data (such as visual inspection of product) shall be clearly described to be easily understood and uniformly applied by those responsible for monitoring.

3.2.7.2 Monitoring procedures (HACCP Principle 4)

Documented monitoring procedures shall be established for each CCP or control measure and shall specify any tests, measurements or observations to assess whether:

- the control measure is functioning as intended;
- the critical limits are met.

The monitoring procedures shall at least include:

- Name or title of personnel responsible for the monitoring and evaluation of monitoring results.
- Monitoring frequency.
- Methods or instructions for tests, measurements or observations to be performed.
- Exact title of the record(s) used to document monitoring results.
- Record keeping instructions (see section 3.2.7.5).

The monitoring methods and frequency shall be able to detect loss of control at the CCP or control measure in time for the product to be isolated before it leaves the control of the facility.

All monitoring devices/equipment requiring maintenance and calibration for accuracy must be controlled through the preventative maintenance and calibration programs.

3.2.7.3 Deviation procedures (HACCP Principle 5)

Documented deviation procedures shall specify any planned or appropriate corrective actions to be taken when monitoring results demonstrate that:

- the control measure is not functioning as intended;
- the critical limits are not met.

The deviation procedure shall at least include:

- Name or title of personnel that have the responsibility and authority to take actions.
- Instructions on corrective actions to be taken.*
- Exact title of the record(s) used to describe the deviation and to document all actions taken in response to a deviation.
- Record keeping instructions (see section 3.2.7.5).
* The deviation procedure for a CCP or control measure shall at least instruct the responsible employees to perform and document the following activities:

- Describe the deviation and its cause.
- Take immediate action(s) to control affected or potentially affected product(s).**
- Implement corrective action(s) to restore control of the CCP.
- Verify the effectiveness of corrective action(s) to ensure that the parameter(s) controlled at the CCP or control measure is appropriately managed.
- Implement measures to prevent reoccurrence of the deviation.
- Verify the effectiveness of preventative measures taken.

** When product is affected or potentially affected, individual with authority shall:

- prevent the on-going production of non-compliant product;
- control the non-compliant product that has been produced;
- assess if other products are implicated in relation to the cause of the deviation;
- perform an assessment of the affected product to determine if the product may be released (see section 3.2.7.3.1);
- Determine the disposition of non-compliant product (see section 3.2.7.3.2).

Documented procedures shall be established and maintained for the appropriate handling of potentially unsafe products to ensure that they are not released until they have been evaluated.

When an unforeseen hazard is identified, the company should perform a reassessment to determine whether the newly identified hazard should be incorporated into Gluten-Free Management System.

Any deviation at a CCP or control measure will require an evaluation of the supporting PC(s), where appropriate, as part of the deviation procedures associated with that CCP or control measure.

3.2.7.3.1 Assessment for release

No product that is injurious to health or otherwise adulterated as a result of the deviation may be allowed to enter commerce. When found to be in deviation, each lot of product shall only be released as acceptable when any of the following conditions apply:

- Evidence other than the monitoring data demonstrates that the CCP or control measure has been effective.
- Evidence shows that the combined effect of multiple control measures for that particular product complies with the identified acceptable levels for the hazard(s) concerned.
- The results of sampling, analysis and/or other verification activities demonstrate that the affected lot of product complies with the identified acceptable levels for the hazard(s) concerned.

The controls and results of the assessment shall be documented.

3.2.7.3.2 Disposition of non-compliant product

Following assessment, if the lot of product is not acceptable for release it shall be handled by one of the following activities:
• Reprocessing or further processing within or outside the facility, as per applicable regulatory requirements, to ensure that the hazard is eliminated or reduced to acceptable levels, or
• Destruction and/or disposal as waste.

The disposition of the non-compliant product shall be documented.

3.2.7.4 Verification procedures (HACCP Principle 6)

Verification is the application of methods, procedures, tests, sampling and other evaluations, in addition to monitoring, to determine whether:

• A CCP or control measure is or has been operating as intended;
• Monitoring and deviation procedures are conducted according to the written program;
• The record keeping meets the requirements defined in 3.2.7.5;
• The CCP’s or control measures are managed;
• There are trends in monitoring results that may indicate development towards loss of control.

Documented verification procedures shall be established and shall at least include:

• Name or title of personnel responsible for the verification.
• Verification frequency.
• A description of the activities to be conducted, including but not limited to:
  - Direct observation of monitoring activities;
  - Interview of persons responsible for monitoring and deviation procedures;
  - Direct observation of corrective actions taken, if possible;
  - Review of records documenting the monitoring activities;
  - Review of records documenting the actions taken in response to a deviation;
  - When applicable, product testing to confirm that the CCP or control measure is properly implemented and achieves the intended outcome.
• Deviation procedures when the results of the verification demonstrate that:
  - The monitoring or deviation activities are not conducted according to the written program.
  - The CCP or control measure is not effective to maintain control of the hazard.
  - There is a trend towards a loss of control.
• Exact title of the record used to document verification results.
• Record keeping instructions (see section 3.2.7.5).

Note: A distinction should be made on the verification record to differentiate between a record review and an on-site observation.

Verification shall be carried out by someone other than the person who is responsible for performing the monitoring activities (i.e. Verifiers cannot verify their own work).

The frequency of verification should be sufficient to confirm that the CCP or control measure remains in control of any hazards. For example, at a dairy plant, staff responsible for the daily monitoring of the pasteurization step fails to take the necessary corrective action. Verification conducted once per month will not be frequent enough to prevent a broad-based recall.

3.2.7.5 Record keeping (HACCP Principle 7)

Records shall be kept to demonstrate the effective application of the critical control points and to facilitate official verifications by the GFCP Approved Auditor or other competent authority.
Records shall be established to document:

- the monitoring results, including, when necessary, the recording of quantifiable values (e.g., temperature, time, Aw, pH) as prescribed in the CCP’s or control measures;
- all information and actions taken in response to a deviation identified as a result of monitoring and verification;
- the verification results.

Records must be up-to-date, legible, accurate and properly filed.

Each entry on a monitoring, deviation or verification record shall include the date and the exact time of the event, and shall be signed or initiated by the employee making the entry using a permanent ink pen or, where computer records are used, electronically.

Deviation records shall identify a target date for completion of preventative measures. Any incorrect entry made to a record and subsequently changed shall be crossed out and initialed by the employee making the change.

### 3.2.8 Process controls

Where more than one step in an overall process may contribute to the reduction of a particular hazard, process controls may be developed for the early points of the process where the hazard cannot be fully controlled, but a subsequent step will result in the elimination or reduction of this particular hazard to an acceptable level. This final control would be determined to be a CCP or control measure.

Operators may also develop process controls, where multiple process steps provide control over one specific hazard. These operators should validate the entire procedure to demonstrate that their process control meets all of the necessary parameters and is effective.

Each PC shall be documented and shall include the following information:

- Product safety hazard(s) to be controlled at the PC;
- The CCP or control measure number to which the PC is linked;
- Monitoring procedures (see section 3.2.8.1);
- Deviation procedures (see section 3.2.8.2);
- Verification procedures (see section 3.2.8.3).

The record keeping shall meet the requirements defined in section 3.2.8.4.

The PCs shall be updated whenever there are changes associated with the process control requirements and reassessed at least annually.

#### 3.2.8.1 Monitoring procedures

Documented monitoring procedures shall specify any tests, measurements or observations to assess whether the process control standards are met.

The monitoring procedures shall at least include:

- Name or title of personnel responsible for the monitoring and evaluation of monitoring results.
- Monitoring frequency.
- The standard(s) to be met.
• Methods or instructions to take measurements, perform tests or conduct observations.
• Exact title of the record(s) used to document monitoring results.
• The record keeping instructions (see section 3.2.8.4).

### 3.2.8.2 Deviation procedures

Documented deviation procedures shall specify any planned or appropriate corrective actions to be taken when monitoring results demonstrate that the PC standards are not met.

The deviation procedure shall at least include:

• Name or title of personnel that have the responsibility and authority to take actions.
• Instructions on corrective actions to be taken.*
• Exact title of the record(s) used to describe the deviation and to document all actions taken in response to a deviation.
• The record keeping instructions (see section 3.2.8.4).

* The deviation procedure for process controls shall at least instruct the responsible employees to perform and document the following activities:

• Describe the deviation and its cause.
• Implement corrective actions to restore control of the PC.
• Verify the effectiveness of corrective actions taken.

If the immediate actions are not found to be effective, the following additional activities must be performed and documented:

• Perform an immediate monitoring activity at the related downstream CCP or control measure to assess potential product impact.
• Implement measures to prevent reoccurrence of the PC deviation.
• Verify the effectiveness of preventative measures for the PC deviation.

### 3.2.8.3 Verification procedures

Documented verification procedures shall specify any planned sequence of observations, tests and other evaluations, in addition to monitoring, to determine whether:

• monitoring and deviation procedures are conducted according to the written program;
• the record keeping meets the requirements defined in section 3.2.8.4;
• the controls in place are effective to meet the PC standards.

The verification procedures shall at least include:

• Name or title of personnel responsible for the verification.
• Verification frequency.
• A description of the activities to be conducted, including but not limited to:
  - direct observation of monitoring activities;
  - interview of persons responsible for monitoring and deviation procedures;
  - direct observation of corrective actions taken, if possible;
  - review of records documenting the monitoring activities;
  - review of records documenting the actions taken in response to a deviation.
• Deviation procedures when the results of the verification demonstrate that:
  - the monitoring or deviation activities are not conducted according to the written program;
  - the PC is not effective to maintain control of the standards.
• Exact title of the record used to document verification results.
• The record keeping instructions (see section 3.2.8.4).

Verification shall be carried out by someone other than the person who is responsible for performing the monitoring activities (i.e., verifiers cannot verify their own work).

3.2.8.4 Record keeping

Records shall be kept to demonstrate the effective application of the process controls and to facilitate official verifications by the GFCP 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 process control.
• all information and actions taken in response to a deviation identified as a result of monitoring and verification.
• the verification results.

Records must be up-to-date, legible, accurate and properly filed.

Each entry on a monitoring, deviation or verification record shall include the date and the exact time of the event, and shall be signed or initialed by the employee making the entry using a permanent ink pen or, where computer records are used, electronically.

Deviation records shall identify a target date for completion of preventative measures.

Any incorrect entry made to a record and subsequently changed shall be crossed out and initialed by the employee making the change.

3.3 Validation

Every facility shall demonstrate that the critical control points or equivalent are capable, on a consistent basis, of achieving the intended level of hazard control.

Validation is performed at the time the CCP or control measure is designed, or when changes indicate the need for re-validation. Validation of a CCP or control measure is, whenever possible, performed before it is fully implemented.

Depending on the CCP or control measure that is being validated, the validation documentation may include:

• Scientific, technical or regulatory support to demonstrate that the selected critical limit is effective for control of the hazard.
• Commissioned testing data specific for a piece of equipment (e.g. pasteurizer) to demonstrate that the equipment is capable of meeting the selected critical limit.
• Supporting data to demonstrate that the monitoring procedures are effective enough to detect loss of control at a CCP or control measure before the finished product leaves the control of the facility.
The GFCP Approved Auditor may request validation documentation for novel control measures covered by pre-requisite programs that have an immediate impact on gluten-control (e.g. new technology for testing).

For more information on the validation process, the ACG recommends the *Guidelines for the Validation of Food Safety Control Measures* developed by the Codex Alimentarius Committee.

3.4 Maintenance and Reassessment of the Gluten-Free Management System

3.4.1 Gluten-Free Management System maintenance procedures

Whenever any changes or situations occur that could affect the hazard analysis or alter the Gluten-Free Management System, the facility shall:

- update the parts of the Gluten-Free Management System affected by the changes or situations;
- reassess completeness and effectiveness of the updated part of the Gluten-Free Management System;
- re-validate all CCP’s or control measures affected by the changes.

Here are examples of potential triggers which could lead to the need to update and/or to perform a reassessment of parts of the Gluten-Free Management System:

- New regulatory requirements related to product safety and gluten-free
- New product
- Non-compliant situations identified during monitoring and verification activities
- Consumer/client complaints
- Product recalls
- Unsatisfactory laboratory results
- Non-conformity identified during GFCP audits or surveys done by government agencies such as the national, regulatory competent authority
- New product line that can potentially cause cross-contamination
- New ingredients or incoming materials that come in contact with the product or are used for preparing the product
- New process step
- New technology or piece of equipment that impacts on the level of a hazard
- New/ongoing construction or change in the product flow and or employee traffic patterns resulting in a potential for cross contamination
- New control measure for an identified hazard
- Change made in product formulation or preparation
- Change made in production volume which impacts on the product flow, sanitation schedule, employee training, etc.
- Change made in the application of a CCP or control measure (e.g. change in critical limit)

The facility has and implements documented procedures to ensure that the Gluten-Free Management System is effectively maintained.

The procedures shall include as a minimum:

- name or title of personnel responsible to make changes to the Gluten-Free Management System;
- name or title of personnel responsible to ensure that the changes are implemented effectively;
- a method to identify the revised versions;
- the use of a log book or equivalent which must at least contain the following information:
a description of the changes;
- the signature or initials of responsible person who made the change;
- where the changes occurred in the Gluten-Free Management System;
- the dates when changes are implemented, reassessed and, if necessary, validated;
- the signature or initials of responsible person who ensure that the changes are implemented effectively;
- the revision date or number that correlates with document changed.

Benefits of implementing effective maintenance procedures:

- Gluten-Free Management System documents are approved for adequacy by competent personnel prior to issue.
- Changes are identified when a situation affecting the hazard analysis occurs which demonstrates effective maintenance of the Gluten-Free Management System to the GFCP Approved Auditor or other competent authority.
- Revised versions are identified.
- Relevant versions of applicable documents are available at points of use.
- Unintended use of obsolete documents is prevented.

3.4.2 3.4.2 Gluten-Free Management System Re-assessment Procedures

Whenever any changes or situations occur that could affect the hazard analysis or alter the Gluten-Free Management System, the facility shall reassess completeness and effectiveness of the updated part of the Gluten-Free Management System and document the reassessment activities conducted in the Gluten-Free Management System modification log book as described in 3.4.1.

At least annually, the facility shall reassess its entire Gluten-Free Management System to determine whether the system:

- is up to date;
- identifies all productsafety hazards;
- has control measures in place for all productsafety hazards which may be controlled by the facility;
- results in the desired outcomes;
- conforms to current regulatory and GFCP requirements;
- conforms to the requirements defined in the Gluten-Free Certification Program Manual.

Documented reassessment procedures shall be established and shall include but are not limited to:

- The individual(s) responsible for the reassessment activities.
- The frequency of reassessment activities or details and specifics of reassessment activities (i.e., the facility may specify that the required reassessment activities are conducted at various times over the course of the year).
- A review of the changes made to the Gluten-Free Management System (see section 3.4.1).
- A review of the actions taken in response to situations indicating a trend toward or a loss of control to ensure that the applicable sections of the Gluten-Free Management System have been updated and reassessed accordingly. The following situations shall be included in the review:
  - client or consumer product safety related complaints;
  - unsatisfactory laboratory results;
  - non-compliant situations identified during monitoring and verification activities;
  - non-compliant situations resulting in a recall;
  - non-conformity identified during GFCP or government audits.
• A review of the product descriptions, list of ingredients and incoming materials, process flow diagrams and schematic diagrams to ensure that they:
  - are up to date;
  - identify all product safety hazards including gluten.
• A review of all hazards identified in the Gluten-Free Management System in order to ensure that:
  - they are accurate;
  - control measures are identified.
• A review of the Pre-Requisite Program(s), Process Control(s) and CCP or equivalent to ensure that they:
  - are up to date;
  - result in the desired outcomes;
  - conform to regulatory requirements;
  - conform to the requirements defined in the Gluten-Free Certification Program.
• A written review, a record review and an on-site assessment of all pre-requisite programs to ensure that they:
  - are up to date;
  - conform to regulatory requirements;
  - conform to the requirements defined in the Gluten-Free Certification Program Manual;
  - are conducted according to the written programs;
  - result in the desired outcomes.
• A review of the records used to document monitoring, deviation and verification results to ensure they are designed to provide all information required in the Gluten-Free Certification Program Manual.
• Exact title of record(s) used to document:
  - reassessment results;
  - changes made to the Gluten-Free Management System;
  - any other corrective actions taken.

3.5 Forms

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Form 1</th>
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<tbody>
<tr>
<td><strong>Process/product type name:</strong></td>
<td></td>
</tr>
<tr>
<td>1. Product name(s)</td>
<td></td>
</tr>
<tr>
<td>2. Important product characteristics</td>
<td></td>
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<td>3. Intended use</td>
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<td>4. Packaging</td>
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<td>5. Shelf life</td>
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<td>6. Where it will be sold</td>
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<td>7. Labeling instructions</td>
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<tr>
<td>8. Special distribution control</td>
<td></td>
</tr>
</tbody>
</table>

Date: ____________________  Approved by: ____________________
### List of Product Ingredients and Incoming Materials

<table>
<thead>
<tr>
<th>Process/Product name:</th>
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<tbody>
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**Date:** ____________  **Approved by:** ____________

### Process Flow Diagram

<table>
<thead>
<tr>
<th>Process/Product name(s):</th>
</tr>
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</table>

**Date:** ____________  **Approved by:** ____________
Plant Schematic

Process/Product name(s)

Date: _________________  Approved by: __________________

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Hazard Identification

List all chemical hazards related to ingredients, incoming material, processing steps, cross-contamination points.

<table>
<thead>
<tr>
<th>Identified chemical hazards</th>
<th>Controlled at</th>
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Date: _________________  Approved by: __________________
### Hazard Identification

**Form 6**

**Process/Product name(s):**

List all chemical hazards related to ingredients, incoming material, processing steps, cross-contamination points.

<table>
<thead>
<tr>
<th>Identified chemical hazards</th>
<th>Controlled at</th>
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Date: _________________  Approved by: ____________________

### Hazard Identification

**Form 7**

**Process/Product name(s):**

List all physical hazards related to ingredients, incoming material, processing steps, cross-contamination points.

<table>
<thead>
<tr>
<th>Identified physical hazards</th>
<th>Controlled at</th>
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Date: _________________  Approved by: ____________________
## Decision tree – CCP Determination and other Control Measures (PP, PC)

<table>
<thead>
<tr>
<th>Process/Product name</th>
<th>CCP and PC number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify category of hazard (B, C, P)</td>
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<tr>
<td>Identify if food is controlled by prerequisite programs</td>
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</tr>
<tr>
<td>G1. Could a control measure (s) be used by the establishment at any process step?</td>
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<tr>
<td>G2. Is the CCP specifically designed to prevent, eliminate or reduce the likely occurrence of the identified hazard to an acceptable level?</td>
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<tr>
<td>G3. Is the process step intended to prevent, eliminate or reduce the likely occurrence of the identified hazard to an acceptable level?</td>
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<tr>
<td>G4. Do a subsequent step eliminate the identified hazard or reduce the likely occurrence to an acceptable level?</td>
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<tr>
<td>G5. Does the step provide partial control of the identified hazard?</td>
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<tr>
<td>Yes = indicate actual prerequisite program (s) and proceed to the next identified hazard</td>
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<tr>
<td>No = proceed to G1</td>
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</table>

### Hazards Not Controlled by the Establishment

<table>
<thead>
<tr>
<th>Process/Product name(s):</th>
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<tbody>
<tr>
<td>List any biological, chemical and physical hazards that are not controlled by the establishment</td>
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</table>

<table>
<thead>
<tr>
<th>Hazards</th>
<th>Indicate how the hazard could be addressed (cooking instructions, public education, “use before” date, etc.)</th>
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Date: ___________________  Approved by: ___________________
## Critical Control Points

<table>
<thead>
<tr>
<th>CCP number</th>
<th>Hazard Description and Control measure</th>
<th>Critical Limits</th>
<th>Monitoring Procedures</th>
<th>Deviation Procedures</th>
<th>Verification Procedures</th>
<th>HACCP Records</th>
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**Date:** __________________  **Approved by:** __________________

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**EXAMPLE OF AN EQUIVALENT FORM – FSEP FORMS 5, 6, 7, 8 AND 9 COMBINED INTO ONE FORM**

### Hazard Identification and Decision tree – CCP Determination and other Control Measures (PP, PC)

<table>
<thead>
<tr>
<th>Process/Product name</th>
<th>CCP number</th>
<th>Hazard Identification and Decision tree – CCP Determination and other Control Measures (PP, PC)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td><strong>Hazard Identification and Decision tree – CCP Determination and other Control Measures (PP, PC)</strong></td>
</tr>
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</table>

**Date:** __________________  **Approved by:** __________________
Section 4- Recognition and Licensing Process

This section details the process for the recognition of facilities and the licensing applied by the ACG under the Gluten-Free Certification Program. The program has been designed to accommodate any product from any size facility.

Those facilities already operating with documented pre-requisite programs and product safety systems which are audited under a third party will be at a distinct advantage. However, the ACG is willing to work with all facilities to fill any gaps in their practices and the requirements of the Gluten-Free Certification Program.

It is expected that a facility exclusively dedicated to the manufacture and/or distribution of gluten-free products will have less complex Gluten-Free Management System. For the other facilities where the influences of other ingredients or products having gluten come into play, the Gluten-Free Management Systems will need to incorporate virtual barriers to ensure that the resulting products claimed to be gluten-free conform to the Gluten-Free Certification Program requirements.

The ACG respects the fact that most facilities are trying their best and are investing significant time and resources in developing their customized Gluten-Free Management System. The ACG pledges to handle all applications in an efficient, credible, transparent and fair manner while also respecting privacy and security of information.

4.1 President’s responsibilities

The President is responsible for:

- providing the applicant with all pertinent information concerning the recognition and/or licensing of a facility;
- providing interpretation of requirements for Gluten-Free Certification Program as applied to a facility to the applicant as well as to the ACG resources (e.g. GFCP Approved Auditors);
- providing guidance to the applicant and direction to ACG resources with respect to issues related to Gluten-Free Certification Program;
- ensuring the communication of all information related to the Gluten-Free Certification Program between ACG resources and applicants flow appropriately (e.g. securely).

4.2 Recognition process steps

The process covers 6 steps, as follows:

- The facility submits an application requesting recognition and/or licensing by the ACG (see section 4.2.1)
- The GFCP Approved Auditor holds a pre-meeting with the facility’s management (see section 4.2.2)
- The facility submits and/or provides access to documentation (see section 4.2.3)
- The GFCP Approved Auditor reviews the facility’s Gluten-Free Management System documentation (see section 4.2.4)
- The GFCP Approved Auditor conducts an on-site audit of the facility’s Gluten-Free Management System (see section 4.2.5)
- The GFCP Approved Auditor reviews the combined information and issues official notification to facility of their Gluten-Free Management System status (see section 4.2.6)

4.2.1 Application requesting facility recognition and/or license

To begin the evaluation process, a facility must submit a completed application to the President which declares that the facility is committed to:
- a pre-requisite program which is current and in place;
• a conform to the requirements of the Gluten-Free Certification Program and that a Gluten-Free Management System has been developed appropriately and is currently implemented;
• provide information in confidence to the ACG or to anyone authorized by it in order that it may be credibly and expeditiously evaluated its conformity with the requirements of the Gluten-Free Certification Program.

4.2.2 GFCP Approved Auditor pre-meeting with the facility's management

After receiving the facility's completed application, the GFCP Approved Auditor schedule a pre-meeting with the facility to:

• provide information about the recognition and licensing, and
• review a random selection of components from the facility written pre-requisite programs and its Gluten-Free Management System.

4.2.3 Submission of the Gluten-Free Management System documentation package

The facility must provide the GFCP Approved Auditor with a documentation package that includes the following:

• senior management letter of commitment (see section 2.2.1);
• Gluten-Free Management System performance reporting procedure (see section 2.2.5);
• name of Gluten-Free Management System team leader (see section 2.2.2);
• pre-requisite programs (see section 3.1);
• list of all products to be produced in the facility and grouped under their respective Gluten-Free Management System;
• Gluten-Free Management System (see section 3.2);
• process control(s), when applicable (see section 3.2.8);
• validation data of critical control points (see section 3.3);
• Gluten-Free Management System maintenance and reassessment procedures (see section 3.4);
• internal audit results. *

* The facility must conduct periodic internal audits in order to ensure that its Gluten-Free Management System is being implemented and is effective. Documentation must be available to support the internal audit. The facility must have corrected any deficiencies identified during the internal audit or provided a plan of action to address such deficiencies.

If the documentation package is incomplete, the applicant will be notified in writing by the ACG or their designate of the deficiencies and asked to submit the incomplete items.

4.2.4 GFCP Approved Auditor review of the Gluten-Free Management System documentation package

The GFCP Approved Auditor will review the entire Gluten-Free Management System documentation package and communicate any unacceptable items to the applicant in writing for correction prior to final on-site audit.

The GFCP Approved Auditor will follow-up on unacceptable items prior to the on-site audit.

4.2.5 GFCP Approved Auditor on-site audit of the facility's Gluten-Free Management System

The on-site audit determines whether the Gluten-Free Management System has been implemented as described in the written programs and is effective in meeting the objectives and requirements of the Gluten-
Free Certification Program. The on-site audit is initiated only after the GFCP Approved Auditor has deemed the facility's written Gluten-Free Management System complete.

The Gluten-Free Management System Team leader or an on-site liaison person must be available during the on-site audit.

The GFCP Approved Auditor will be made available as deemed appropriate and agreeable to the applicant.

At the conclusion of the on-site audit, there will be a written report including any non-conformity identified during the on-site audit.

Prior to recognizing a facility, the GFCP Approved Auditor must confirm that all non-conformities have been corrected by the facility.

4.2.6 GFCP notification recognizing the facility or issuing a license under the Gluten-Free Certification Program

The President will issue an official notice to the facility's management confirming that the GFCP Approved Auditor has reviewed the facility's Gluten-Free Management System and found that it currently meets all of the Gluten-Free Certification Program requirements.

Section 5- Changes to a recognized Gluten-Free Management System

5.1 New Gluten-Free Management System

When a facility adds a new Gluten-Free Management plan to its operations, it must be communicated to the ACG or its designate prior to the application of the new plan. The ACG or its designate will conduct a review of the new Gluten-Free Management System as soon as possible and encourages facilities to await the evaluation report before starting to use the new process.

5.2 Changes to a Gluten-Free Management System

When a facility changes its recognized Gluten-Free Management System, it must enter the changes in the Gluten-Free Management System log book as described in section 3.4.1 of the Gluten-Free Certification Program Manual. The data must be available for future review by the GFCP Approved Auditor.

5.3 Changes in ownership

If there is a change in ownership in a Recognized Facility or License, even though the originally recognized Gluten-Free Management System is intact and in good standing, the new owner will still be required to submit a new application to the ACG. The application will confirm that the originally accepted Gluten-Free Management System is intact and will not be changing as a result of the change in ownership. The application will also confirm the commitment of the new owner as well any changes in accountabilities as per the Gluten-Free Certification Program Manual.

If significant changes to the Gluten-Free Management System are made (see sections 5.1 and 5.2), the new owner will be required to submit the application and a list of the changes made to the Gluten-Free Management System to the ACG. The ACG will evaluate the impact of the changes on the Gluten-Free Management System and determine if the facility has to undertake an evaluation process as if it were a new applicant.
Section 6 - GFCP Evaluation and Audit of Recognized Facilities and Licensees

This section describes to industry how the GFCP Approved Auditor will verify conformity of facilities to the requirements of the Gluten-Free Certification Program. An evaluation would be done at the time of application to verify the documentation package is complete and could be done remotely or on-site as deemed appropriate. An audit would be conducted solely on-site and focuses on the operation and functionality of the Gluten-Free Management System. The following will focus on audit of the Gluten-Free Management System.

6.1 Objective

The objective of the verification by the GFCP Approved Auditor is to confirm that the facility’s Gluten-Free Management System:

- is up-to-date;
- has been effectively reassessed;
- meets the requirements of the Gluten-Free Certification Program;
- is implemented as described;
- is supported by its Senior Management.

6.2 Frequency of audit

The audit frequency will be once a year and dependent on whenever the following situations occur:

- submission of new Gluten-Free Management System.
- follow-up after a recall.
- laboratory results or audits demonstrate that the facility is not delivering its Gluten-Free Management System or fails to conform to other aspects of the requirements of the Gluten-Free Certification Program
- other audit protocol or sampling results deemed to be relevant

6.3 Audit scope

The audit scope may include a review of:

- the Gluten-Free Management System performance reporting process;
- the Gluten-Free Management System;
- the pre-requisite programs;
- the maintenance and reassessment procedures.

The scope selection will be based on GFCP Approved Auditor evaluation of all information available to it including audit results and other situations that have occurred at the facility.

6.4 Opening meeting

The following information will be given and confirmed during the opening meeting with the facility representatives:

- introduction of GFCP Approved Auditor staff or designate and their titles and roles;
- the objective and scope of the audit;
- the audit schedule and procedures;
- the estimated date and time for the closing meeting.
6.5 Gathering objective evidence to determine conformity

The GFCP Approved Auditor will gather objective evidence to confirm whether or not the Gluten-Free Management System:

- is up-to-date;
- has been effectively reassessed;
- meets the requirements of the Gluten-Free Certification Program;
- is implemented as described;
- is supported by Senior Management.

The GFCP Approved Auditor will gather objective evidence by:

- reviewing documentation and records;
- observing procedures being implemented;
- interviewing/questioning a selection of employees.

6.6 Communication of results and actions required

Results of the audit are communicated to the facility through a report during the closing meeting and followed up with a formal written report as soon as possible.

The audit report includes the following information:

- Scope of the audit.
- Corrective Action Request(s) (CAR).
- Conclusions (overall comments on the result of the audit).

A CAR is issued to a facility whenever non-conformity is determined. The CAR identifies the non-conformity and requires the facility to implement corrective measures by:

- providing an acceptable action plan by a specified date;
- effectively implementing the corrective and preventative measures as described in the action plan by a specified date.

6.7 Request for review of a CAR

A facility may request a review of a CAR before the date specified for the submission of an action plan. The facility must submit its reason for the request in writing, to the GFCP Approved Auditor. A written decision is forwarded back to the facility.

If the CAR is upheld, the facility must submit an acceptable action plan and correct the non-conformity noted by the dates specified by the GFCP Approved Auditor. If the CAR is overturned, the CAR will be cancelled.

6.8 Acceptable action plan

An acceptable action plan is to be submitted by the facility to the GFCP Approved Auditor by the date specified when the CAR was issued. The entire action plan must be implemented by the facility by the specified date for completion of corrective measures stated on the CAR.
The following describes each component of an acceptable action plan as well as the objectives of each component.

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**Component 1 - Description of the problem**

The objective is to accurately describe the problem, which will assist to identify the:

- Action to be taken on affected or potentially affected product.
- Immediate measures necessary to restore control of the deviation.
- Root cause(s).

Facilities must collect information to find out the exact problem remembering that one situation of non-conformity may be the result of multiple problems or causes.

- What is the non-conformity?
- Did the problem affect product?
- Where is the problem located?
- How widespread is this problem?
- When did the problem occur?
- Who is involved in this problem?
- Is this the first time the problem occurred?

**Written Action Plan**

- Describe the problem as it relates to the non-conformity noted on the CAR.

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**Component 2 - Person(s) responsible for measures**

The objective is to determine the people who have the knowledge, time, authority and competence to correct the non-conformity.

**Written Action Plan**

- Identify the name or title of person(s) responsible for the immediate/short term and preventative measures.

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**Component 3 - Description of Immediate /short term measures**

The objectives are to:

- Control affected product or other thing(s).
- Take immediate measures to restore control over the deviation so that products are produced within the requirements of the Gluten-Free Certification Program.

**Written Action Plan**

- Describe the measures taken on affected or potentially affected product.
- Describe the results of the assessment completed to determine if other products were implicated.
Describe the assessment performed or to be performed on the affected or potentially affected product including any disposition of product.

Describe the immediate or short term measures taken to restore control over the deviation until permanent and preventative measures are planned and implemented.

Describe the procedure to verify the effectiveness of immediate or short term measures taken.

Note: Depending on the impact of the non-conformity, immediate measures may or may not be required.

Component 4 - Identification of root cause(s)

The objective is to identify the root cause(s) so facilities can form appropriate and comprehensive corrective measures that will prevent the recurrence of the deviation.

Start with the problem description:

- Why has the GFCP Approved Auditor found the deviation and not the facility?
- Identify all potential causes (Environment, Equipment, Personnel, Training, Written Programs, etc.).
- Some causes have already been corrected by immediate measures.
- Identify the root cause(s).

Written Action Plan

- Describe root cause(s).

Component 5 - Description of Preventative measures

The objective is to identify and implement measures to eliminate the root cause(s) and prevent recurrence of the deviation.

Written Action Plan

- Describe the preventative measures.
- Establish a date for completion of each planned preventative measures.

Component 6 - Description of activities planned to verify the effectiveness of preventative measures

The objective is to provide feedback as to whether or not further adjustment is necessary to the Gluten-Free Management System.

The assessment is the application of temporary procedures, tests or other evaluations to determine the effectiveness of the measures taken to correct the problem.

Examples:

- On-site assessment of measures taken.
- Ensuring that staff are adhering to new procedures or instructions by observing and interviewing them.
• Temporarily increasing sampling.
• Temporarily increasing monitoring procedures.

If the problem is not resolved:

• Additional corrective measures are required.

**Written Action Plan**

• Describe the activities planned to verify the effectiveness of preventative measures.
• Establish a date for completion.

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6.9 **Action plan extension**

The ACG may grant an extension to the specified date for completion of the action plan under the following circumstances:

• Product safety or gluten-free status of products are not compromised;
• The facility will not meet the specified date for completion of corrective actions due to reasons beyond its control;
• The facility submits a written request for an extension before the specified date for completion of the action plan;
• The written request includes the reason for the extension request and the proposed new completion date.

The facility must submit its reasons, in writing, to the ACG and or the GFCP Approved Auditor.

6.10 **GFCP follow-up**

After the date for completion of corrective measures has passed, the GFCP Approved Auditor will follow up at the facility to ensure that the corrective measures have been completed as described and are effective. If the corrective measures have been implemented effectively, the CAR is closed. If the corrective measures have not been effectively implemented, the CAR remains open and the ACG or the GFCP Approved Auditor will take the following actions:

• A warning letter is sent to the facility's management.
  - The warning letter informs the facility that a failure to implement effective corrective measures by the date specified in the warning letter will result in the loss of status as a recognized facility or licensee under the Gluten-Free Certification Program.
• A follow-up evaluation of corrective measures is conducted after the date specified in the warning letter.
• If the corrective measures have been implemented effectively, the CAR is closed.
• If the corrective measures have not been implemented effectively, the facility will lose status as a recognized facility or licensee under the Gluten-Free Certification Program and fall under suspension or the recognition or license will be cancelled.
• All the above would be subject to the results of any appeal that the facility formerly brings forward. This would be considered by an expert committee established solely at the discretion of the ACG or designate and all decisions are final and made in writing.

6.11 **Suspension or Cancellation**

When a facility loses status under the Gluten-Free Certification Program, the ACG or designate will send a letter to the facility's management informing them that the facility is suspended with conditions or is cancelled.
Suspension of a recognition or license will temporarily and conditionally render the facility ineligible to participate and access the benefits of the Gluten-Free Certification Program.

Cancellation will completely render the facility ineligible to participate and receive the benefits of the Gluten-Free Certification Program. In the case of cancellation, the facility will no longer be eligible to use and must withdraw any product or labels with the Gluten-Free Certification Program Trademark(s) applied including similar words or any advertising making claims regarding their former status under the Gluten-Free Certification Program.

If a facility wishes to return to the Gluten-Free Certification Program, it must re-apply like a new applicant showing that they have investigated and determined the root cause(s) of the failure of their Gluten-Free Management System and specify corrective measures that they have implemented. The results of the investigation and the corrective measures taken shall be documented in the new application requesting consideration for recognition under the Gluten-Free Certification Program.