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“Certified Free From™” Certification Program Scheme and Standards

Developed and Maintained by MenuTrinfo®, LLC

MenuTrinfo®

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Glossary

Allergen Control Plan (ACP): A systematic method for identifying and controlling allergens, from the incoming Ingredients to the final Product in any Kitchen or Facility. This includes the Top 8 allergens as well as gluten (if applicable) for the CFF certification program.

Allergen: A substance that triggers an immune response.

Allergen-Free: Less than 5 ppm of any given allergen, as determined by an approved allergen test.

Big 8 or Top 8 Allergens: Allergens that make up 90% of the allergic reactions that occur in the United States: egg, fish, milk, peanuts, Crustacean shellfish, soybeans, tree nuts and wheat. These allergens shall be listed on food labels prominently and in consumer-friendly language.

Certification Agreement: The legally binding contract that is signed by the Participant and MenuTrinfo, LLC prior to starting the CFF auditing process.

Certification Scheme: Certification system related to specified Products, to which the same specified requirements, specific rules and procedures apply.

Certification Body (CB): Third-party conformity assessment body operating certification schemes.

Coconut: Although botanically speaking, coconuts are "drupes" rather than nuts, the FDA considers coconut a tree nut for food allergy labeling purposes, and the individual nut shall be specified on the label.

Cross-Contact: Occurs when the proteins from various foods mix, rendering a “safe” food “unsafe.” This can occur in the manufacturing or cooking process by using contaminated machinery, utensils, pans, frying oils, grills, etc. Cross-contact can also occur in the storage, preparation, and serving of food.

Crustacean Shellfish: Any chiefly aquatic arthropod of the class Crustacea, typically having the body covered with a hard shell or crust, including lobsters, shrimps, crabs, and crayfish. Crustacean shellfish are a top 8 allergen in the USA, while molluscan shellfish are not.
Document: A static collection of data that can be revised at any time.

Enzyme-Linked ImmunoSorbent Assay (ELISA): Commonly used immunochemical test that detects proteins, antibodies and other small molecules.

Facility: Physical space where the CFF Product is made.

Gluten: A protein present in cereal grains including wheat, rye, and barley, that is responsible for the elastic texture of dough. Gluten damages the intestine of people with celiac disease.

Gluten-Free: Less than 10 ppm gluten, as determined by an approved Lateral Flow Device test. The FDA defines gluten-free as less than 20 ppm, but CFF has elected to use a lower threshold.

Ingredients: Materials imported from outside suppliers to create the final CFF Product.

Kitchen: Physical space where food is being stored and prepared.

Lateral Flow Device (LFD): Simple test kit intended to detect the presence of a target substance (i.e. allergenic proteins) in a liquid sample.

Log: A document that can be completed.

Participant: The company or organization who has a signed agreement with MenuTrinfo, LLC to complete the audit of their Kitchens or Products.

Polymerase Chain Reaction (PCR): Molecular biological method of determining the presence and amount of specific proteins in very small amounts.

Primary contact: The individual employed by or contracted with the Participant who oversees the maintenance of the CFF Certifications.

Product: Final output that has qualified for CFF Certification.

Record: A completed log (see above).

Sanitize: To make something hygienic by using approved chemicals designed to reduce the number of harmful microorganisms to a safe level.

Supplier: A company or organization who provides Ingredients and other materials to another entity; could also be referred to as vendor or distributor.

Abbreviations

AB – Accreditation Body

ANSI-ANAB – ANSI National Accreditation Board

ACP – Allergen Control Plan

CB – Certification Body

CFF – Certified Free From

FALCPA – Food Allergy Labeling and Consumer Protection Act of 2004

FDA – U.S. Food and Drug Administration

GF – Gluten-Free

GMP – Good Manufacturing Practices

HACCP – Hazard Analysis Critical Control Points

MT – MenuTrinfo, LLC

SOP – Standard Operating Procedure

SSOP - Sanitation Standard Operating Procedures

Introduction and Background

MenuTrinfo, LLC (MT) was started in 2010 by Betsy and Rocky Craig. Originally created as a nutrient analysis and menu labeling consulting company, they quickly realized the need for more reliable and transparent allergen information in both foodservice and retail operations.

After expanding the nutrient database to automatically mark any of the top 8 allergens within a recipe or formulation, the next product offering of the company was created. AllerTrain™ and its Suite of Courses was developed to train all members of the industry how to safely prepare food that is allergen-free and/or gluten-free.

Following the training courses, the MenuTrinfo, LLC Certified Free From™ (CFF) auditing program was released in 2017. The critical steps in avoiding allergen introduction and incidental cross-contact were identified, and a robust audit was put in place to ensure the best practices are implemented at any food manufacturing Facility, commercial Kitchen or bakery, retail establishment or dining area making allergen-free claims.

There are over 32 million Americans who have a food allergy, and many more who are living with or caring for a loved one who is allergic to one or more foods. The CFF seal is a mark of dedication on behalf of the brand, and a source of confidence for consumers who need the safest possible options for themselves or their families and friends.

Disclaimer

This document is for informational purposes only. Following the Certified Free From standards will not prevent a food allergic reaction if there are errors made in Ingredient manufacturing, in manufacturing of the CFF Product, or during shipping. MenuTrinfo, LLC has made every effort to provide accurate information and generally accepted best practices. Following these standards does not replace Good Manufacturing Practices (GMP) and/or HACCP and should be considered a supplemental program.

MenuTrinfo, LLC maintains the right to make changes to the CFF certification program as necessary, with or without prior notice.

Throughout this document, the terms below are defined as follows:

i. “shall” indicates a requirement;
ii. “should” indicates a recommendation;
iii. “may” indicates a permission;
iv. “can” indicates a possibility or a capability.

Participants who are operating a commercial or food service Kitchen rather than a manufacturing Facility should replace “Facility” with “Kitchen” and shall adhere to all applicable standards.

Selection of a CB

At the time of publication, MenuTrinfo, LLC is the only approved Certification Body for the CFF audits and certifications.

If approved in the future, the Participant may work with a CB that is accredited to ISO 17065 and approved by MenuTrinfo to certify to the CFF standards.

Prior to the Participant signing a certification agreement, the CB shall demonstrate that they have sufficient personnel, including coordinators, auditors and reviewers who have been trained against the CFF standards.

The Participant shall also ensure that their selected CB includes the following components in their certification agreement:

i. The Products that will be included in the scope of certification
ii. The CB’s fee schedule

iii. The CB's policies regarding the correction of any non-conformities found during the audit
iv. The conditions that would require the certification to be suspended or withdrawn
v. The methods taken to ensure confidentiality of all proprietary intellectual property that may be shared during the auditing process

CB Requirements

Any CB that is auditing against the CFF scheme shall adhere to the following criteria:

i. The CB shall establish, implement and maintain a procedure for management of competencies of personnel involved in the certification process.
    a. The procedure shall require the CB to determine the criteria for the competence of personnel for each function in the certification process, considering the qualifications laid out below.
ii. The CB shall establish, implement and maintain a procedure for management of competencies of personnel involved in the certification process.
    a. The procedure shall require the CB to identify training needs and provide, as necessary, training programs on verification processes, requirements, methodologies, activities and other relevant qualifications laid out below.

Any CB personnel involved in the audit or review of the CFF certification scheme shall have the following qualifications:

i. Has completed and passed an ANSI-accredited food allergy training course
ii. Has completed and passed an ANSI-accredited food safety course
iii. Has at least five (5) years of experience in the foodservice industry

The CB shall be a legal entity, or a defined part of a legal entity, such that the legal entity can be legally responsible for all its certification activities.

Participant Requirements

In order to be considered for CFF certification, the Participant shall:

i. Be a legal entity that is able to sign a binding certification agreement
ii. Have an insurance policy that covers errors and omissions as it relates to food recalls and consumer complaints

iii. Have full ownership over the Product(s) being certified, and/or owners of the Facility where the Product(s) are made

Application Process

Prior to signing the Certification Agreement, the Participant shall submit an application to the CB. The CB will also share the application and any supplemental materials to MT. The application will include the following:

iv. Name and address of the Facility or Facilities to be audited
v. Description and overview of Products to be certified
vi. Description and overview of the Facility and any allergens present
vii. Allergens to be included as part of the CFF certification
viii. List of any current certifications that are held
ix. Name, phone number and email address of the primary contact

Upon receipt of the application and application fee, the CB will review and either accept or decline the certification of the applicant.

If the CB has no prior experience with the type of Product on the application, or a normative document or scheme that is referenced, the CB shall inform the applicant. At that time, the applicant may choose a CB that is better suited for their needs.

Assignment of Primary Contact

The Participant shall designate a single point of contact for all matters related to the CFF certification, such as document retrieval and audit coordination. Having a single primary contact helps ensure proper communication with the Participant. This is particularly important with Participants that utilize multiple Facilities for the manufacturing and packaging of their CFF Products. While there may be temporary contacts at each individual site, it is the responsibility of the primary contact to oversee all certifications and communication.

The primary contact is also responsible for explaining the testing requirements to any outside Facilities they may utilize. The CB will explain the testing protocol and approve the final testing schedule and plan, but the primary contact shall make any necessary contractual or financial agreements with the Facilities to ensure they are following this standard.

Scope of Certification

The CFF certification is site-specific in the United States, and both site-specific and allergen-specific for Facilities outside of the United States. The certification covers Food and Beverage Products, Pharmaceuticals, Nutraceuticals, Cosmetics, and some Chemicals.

Upon approval of the Participant's application, the scope of certification will be defined. This includes all allergens that will be part of the certification, which Products will be certified, and which Facilities will be involved. All Facilities involved in the manufacturing and distribution of a CFF Product must be disclosed to the CB and are all subject to an on-site audit and annual surveillance audits.

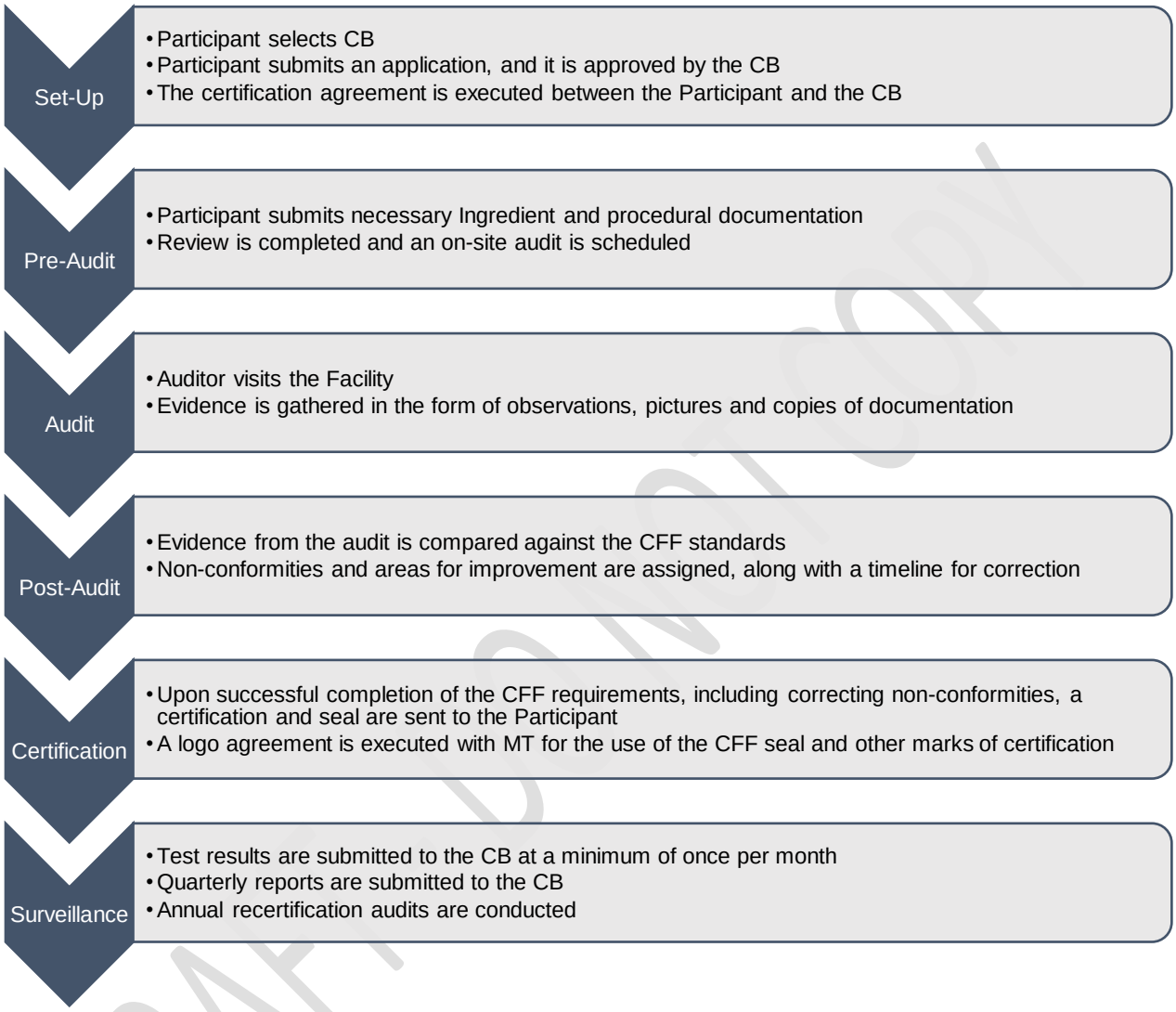
If the Participant elects to include tree nuts as part of the certification, the determination shall be made if that will include coconut or not. MT offers two versions of the CFF seal that include tree nut – one that includes coconut as part of the CFF certification, and one that excludes coconut as it is not botanically considered a tree nut.

The Scope of Certification shall be agreed upon by both the Participant and the CB prior to the initial audit and each annual audit that follows.

If the Participant would like to make changes to the scope, they shall submit that request in writing to the CB. The CB will either approve or deny the request and will provide their rationale. If the change is approved, the CB may choose to conduct an interim audit prior to the next annual audit. They may also determine the change is not major enough to necessitate another audit and will work with the Participant remotely to determine what shall be put in place to be in compliance with the new scope.

To qualify for certification, the Participant must pass the audit following the standards laid out later in this manual and demonstrate ongoing maintenance through allergen testing and surveillance audits.

Auditing Process Overview



Changes Affecting Certification

MT maintains the right to modify the CFF standards from time to time, upon a reasonable notice of not less than fifteen (15) days to the Participant and CB, or any lesser time period as may be reasonably necessary to comply with applicable law, regulation, ordinance, or court order, or to reflect advances in knowledge relating to CFF Products.

The actions to implement changes affecting certification shall include, if required, the following:

i. Evaluation
ii. Review
iii. Certification decision
iv. Issuance of revised formal certification documentation to extend or reduce the scope of certification
v. Issuance of certification documentation of revised surveillance activities (if surveillance is part of the certification scheme)

Pre-Audit Review

Upon execution of the Certification Agreement, the Participant will go through the Pre-Audit Review. The purpose of this step is to review all Ingredients for allergen content and cross-contact concerns, and ensure all necessary documentation is in place prior to sending an auditor on site.

The Pre-Audit Review will require the Participant to submit the following information:

i. Copies of specification sheets or other Supplier-provided documentation that includes allergen information, for all Ingredients used in CFF Products
ii. Copies of reports and certifications from any recent and pertinent audits, such as food safety
iii. Allergen Control Plan documentation
iv. Copies of labels for all CFF Products (as being printed at that time)

During the Pre-Audit Review, any precautionary labeling on Ingredients will be researched by the CB. To be approved for use in CFF Products, the Supplier of the Ingredient shall be able to provide written verification of the allergen-free status of the Ingredient.

If any Ingredients are being imported from outside the United States, additional documentation and/or testing will be required (see CFF Standard 1.2.1).

On-Site Audits

Upon successful completion of the Pre-Audit Review, an on-site audit will be scheduled. The CB will send an auditor who is trained against the CFF Standards and is also familiar with the industry of the Participant.

The on-site audit consists of the following:

i. Introductory meeting with the auditor and primary contact
ii. Documentation review
iii. Facility walk-through
iv. Staff interviews
v. Testing demonstration
vi. Closing meeting

The auditor has five (5) business days from the date of the audit to submit the audit checklist and all evidence to the Reviewer.

At the CB's discretion, additional inspections may be done throughout the year to ensure the standards are being met.

Evaluation

The CB shall only rely on evaluation results related to certification completed prior to the application for certification, where it takes responsibility for the results and satisfies itself that the Body that performed the evaluation fulfills the requirements contained in ISO 17065 and those specified by the Certification Scheme.

The Reviewer shall compare all evidence gathered during the on-site audit and determine if it is enough to meet the CFF standards. They will also assign non-conformities in the following categories:

i. Observation: something that does not deviate from the standards but could be improved

ii. Minor non-conformity: a standard that was not met, but its absence does not pose a threat to a consumer's wellbeing
iii. Major non-conformity: a standard that was not met, and its absence will pose a threat to a consumer's wellbeing

The CB will provide the list of non-conformities to the Participant within ten (10) business days from the date of the on-site audit.

All Minor non-conformities shall be corrected within sixty (60 days) upon receipt of the evaluation report.

All Major non-conformities shall be corrected within thirty (30 days) upon receipt of the evaluation report.

All Observations and non-conformities are reviewed annually (example: if a minor non-conformity is found a second time, then the second time could be reported as a major non-conformity).

To correct a non-conformity, a root cause analysis and corrective action shall be submitted to the Reviewer. If the evidence is sufficient, the non-conformity will be removed from the evaluation report. If the non-conformities are not corrected within the time frames above, certification will not be granted. The Participant would need to re-apply for certification and begin the process again.

Certification

Once all non-conformities have been corrected (if any were assigned), the Participant will be notified of their successful completion of the CFF certification program. The CB will also notify MT of the certification. The final report, which includes a summary of audit findings and the correction of any non-conformities, will be submitted to the Participant and MT within ten (10) days of the final non-conformity correction. The final report is the property of the Participant and will not be shared with any parties outside of the CB and MT without prior permission from the Participant.

Upon delivery of the final report (which is sent electronically), a hard copy of the Participant's certification will be sent in the mail, and a digital copy will be provided via email to the primary contact. If multiple facilities were included in the certification, each would receive their own copy. The certification shall contain the following information:

i. The MenuTrinfo, LLC name and logo
ii. The CFF Seal that corresponds to the Participant's specific certification
iii. Date of certification
iv. Date of expiration (12 months after certification)
v. Participant's name
vi. Facility name (if different than Participant)
vii. Certificate number
viii. Product names included as part of the certification
ix. Signatures of authorized officers from MenuTrinfo, LLC and the CB (if applicable)
x. Accreditation Body logo (if applicable)

A digital copy of the certification will also be sent to MenuTrinfo, LLC, if MT is not the CB.

Should any additional Products be approved by the CB prior to the next surveillance audit, they will be eligible for use of the seal, but will not be added to the physical certificate until after the next surveillance audit. The expiration date applies to every Product being certified at a single Facility and is not dependent on the individual Product's certification date.

While a single Product name is listed on the certificate, a digital copy of all SKUs due to varying packaging will be reported to the CB to include as part of the directory of certified Products.

Surveillance

Ongoing testing and reporting are required from the Participant between annual recertification audits. The final report provided by the CB will include the required testing schedule. At a minimum, an allergen test per CFF allergen shall be conducted once per month. The results shall be submitted to the CB to be reviewed and recorded. Quarterly reports shall also be submitted to the CB. These reports detail any changes to Ingredients or procedures from the past three months.

Throughout the calendar year, any changes to Ingredients, formulations, policies, procedures or packaging shall be sent to the CB for approval prior to the changes being finalized.

The Participant shall be recertified each calendar year. The timing of certification is the same as described above for the initial audit.

Use of the CFF Seal and Marks of Certification

The Participant shall sign a logo use agreement with MT prior to using the certification seal or MT name on any Products, Kitchens or marketing materials. This agreement describes the proper uses of the logos and seals, per the MT brand identity standards.

If the Participant provides copies of the certification documents to others, the documents shall be reproduced in their entirety or as specified in the certification scheme.

In referring to its Product certification in communication media such as documents, brochures or advertising, the Participant is still adhering to all logo use requirements.

The CFF seal and any other marks of certification is prohibited for use if the certification is suspended or withdrawn.

Testing Requirements

CFF Participants shall conduct chemical testing as a means of validating allergen and/or gluten control programs, supporting certification by confirming food is maintaining CFF status, ensuring allergen food safety, and adding value to consumers.

Immunochemical methods are the most specific and sensitive tests for continuous allergen monitoring. The preferred testing method for the CFF certification is the Lateral Flow Device (LFD). LFDs are affordable, easy to use and provide quick results. They can be used on surfaces and finished goods, based on the individual test, and are simple to interpret correctly, as they are a qualitative method of analysis. These tests are valid for Facilities that are dedicated allergen-free, or Facilities that contain allergens, but do not use shared lines with CFF Products.

Facilities that use shared lines to produce CFF Products shall not use LFDs as their sole source of testing. Due to the increased possibility of cross-contact during manufacturing, more sensitive tests are required. A Facility with shared lines shall utilize quantitative testing methods, such as Enzyme-Linked ImmunoSorbent Assay (ELISA) or Polymerase Chain Reaction (PCR). Outside laboratories may be utilized, as long as the outside lab is ISO 17025 accredited.

Upon completion of the CFF audit, the CB will work with the Participant to determine the necessary level of testing, as well as the testing schedule. Participants shall conduct a

minimum of one allergen test per CFF allergen per month. Any deviations from the standard testing schedule shall be approved by the CB and be properly documented.

Validation testing of the specific test kit selected must be conducted prior to its approval by the CB and use by the Participant. The test kit must be used on a surface or product that is known to contain the pertinent allergen. If the test result comes back as expected as a positive result, that will be recorded, and the test kit can be used for the ongoing tests. If the chosen test kit does not provide a positive result due to the surface or Product being tested, then that is not a valid test kit and cannot be used for ongoing tests.

Testing validation shall be done prior to the on-site audit, or after the on-site audit but prior to receiving the certification.

MT considers LFD, ELISA, PCR and/or third-party testing, paired with visual inspection of cleanliness, to be a reasonable and reliable approach for monitoring allergen residues as part of a valid and verified allergen control program.

Suspension or Withdrawal of Certification

If the Participant is found to be violating one of the CFF standards, their certification will either be suspended or withdrawn, depending on the severity of the violation.

The certification may be suspended for the following reasons:

i. The Participant is found to be not following all policies and procedures as displayed to the auditor during the on-site audit
ii. Any evidence provided to correct a non-conformity is found to be falsified
iii. The Participant uses the CFF seal or other marks of certification on any Products that were not included in the Certification Agreement
iv. The Participant uses Ingredients that have not been approved for use by the CB
v. The Participant does not submit monthly allergen test results or quarterly reports
    a. An exception may be granted for Facility closures that don't allow for the manufacturing of Products. In these instances, a written letter shall be provided to the CB to explain the closure and confirm that no Products are actively being manufactured or distributed.
vi. The Participant misrepresents the CFF seal and/or other marks of certification
vii. The Participant has a Product involved in a recall that is not divulged to the CB or MT
viii. The Participant has a positive allergen test that is not submitted to the CB or MT

If a Participant's certification is suspended, they have ten (10) business days to implement any necessary corrective actions. If this is not met, the Participant will have its certification withdrawn. It is up to the discretion of the CB and MT if the Participant may ever apply for certification in the future. If it is determined that the reason for suspension may also present harm to a consumer, the CB and/or MT may require a recall.

If the Participant's certification is withdrawn, any Products using the CFF seal and/or other marks of certification shall be immediately removed from all packaging, and any Products already in the market shall be recalled.

If the Participant shall recall a Product due to allergen content, the CB and MT shall be notified within 24 hours of the incident. Failure to alert the CB and MT of an allergen-related recall will be cause for immediate withdrawal of certification.

Complaints and Appeals

The CB shall have a policy and procedure in place for dealing with any complaints and appeals from Participants, consumers, and MT. If a complaint or appeal is submitted to the CB, it will be reviewed for validity and further action. The CB has ten (10) business days to respond to the complaint or appeal. All complaints, appeals and resolutions shall be documented and kept on file for at least three (3) years.

If the appeal or complaint is regarding an employee of the CB, that employee cannot be involved in the resolution.

Management of Impartiality

The CB shall not, under any circumstances, provide consultation or guidance to a Participant that is actively seeking certification. If the CB chooses to consult with a potential Participant, the Participant shall then wait three (3) years before being eligible to apply for CFF certification.

The CB shall maintain (through publications, electronic media or other means), and make available upon request the following: information about (or reference to) the certification scheme including evaluation procedures, rules and procedures for granting,

for maintaining, for extending or reducing the scope of, for suspending, for withdrawing or for refusing certification.

Record Keeping

All documentation gathered and generated during the auditing process shall be kept on file by the CB for a minimum of three (3) years. During this time, it is the responsibility of the CB to maintain proper security protocols for any proprietary documentation provided by the Participant.

Directory of Certified Products

The CB shall maintain information on CFF Products which contains at least the following:

i. Identification of the Product
ii. The standards and other normative documents to which conformity has been certified
iii. Identification of the Participant

CFF Certification Standards

The following standards shall be met or exceeded by the Participant to qualify for use of the CFF seal and other marks of certification.

It is possible that some standards will not apply to certain Participants. In those instances, written explanation shall be submitted to the CB before or during the initial audit. If deemed acceptable, the standard may be marked as exempt by the auditor along with a qualifying note.

1. Supply Chain

1.1. Ingredient and Supplier Approval

1.1.1. The Participant's Allergen Control Plan (ACP) shall contain a policy and/or procedure on how new suppliers are vetted and approved. All Ingredients shall be purchased from approved suppliers.

1.1.2. All Ingredients shall be properly vetted for allergens prior to entering the Facility. The following criteria shall be met for Ingredients that are sourced from within the United States:

1.1.2.1. The ACP shall contain a procedure to identify and approve Ingredients.

1.1.2.2. The process to approve new Ingredients includes evidence that demonstrates that all incoming materials meet the CFF standards.

1.1.2.3. The documentation required depends on the level of uncertainty relating to the Ingredient.

1.1.2.4. Specification sheets, or other documents that include adequate allergen information, as well as other required documentation such as testing results shall be on file for every Ingredient.

1.1.3. The ACP shall contain a written policy regarding the continuous validation of allergen-free Ingredients.

1.1.3.1. All approved Suppliers shall be required to tell the Participant if there has been a change to the allergen status of the Ingredient(s) they supply prior to the change.

1.1.3.2. Participants shall request updated specification sheets as well as any other required documentation as necessary.

1.1.4. Spot purchases are not allowed, as there is not adequate time to fully vet the Ingredient before use in a CFF Product.

1.1.5. Ingredient changes shall be reported to MenuTrinfo, LLC prior to their introduction to a certified Product. New Ingredients shall go through the full vetting and approval process before they can be used in CFF Products. Certification is **not valid** if Ingredients are being used prior to the CB's approval.

1.2. Ingredient and Supplier Approval – Imported Directly from Outside the United States

1.2.1. Ingredients that are being imported directly from countries outside the United States shall be thoroughly vetted to ensure they align with the standards set in FALCPA. Foreign Suppliers need to provide specification sheets, or other documents that include adequate allergen information, as well as other pertinent documentation such as testing results. At times, they will be required to sign an affidavit regarding their allergen controls, or the Products may need to be tested prior to entering the Participant's Facility.

1.3. Traceability and Recalls

1.3.1. The Participant shall provide a complete list of Products that will be CFF allergens and/or gluten. This list shall be maintained by the Participant. The CB shall be notified of an upcoming Product change immediately. The updated list shall be sent within three (3) days of approved change.

1.3.2. Purchasing documents shall be created, used, revised and maintained for a minimum of 3 years to ensure the correct Ingredients are being ordered and received.

1.3.3. The ACP shall include a two-way traceability (trace forward and trace backward) process for all Ingredients and Products. The traceability shall also account for any rework material, if applicable.

1.3.4. The Facility shall conduct a mock recall at least once per year.

1.3.5. The ACP shall include a policy on how reworked materials are handled. The policy shall include clear instructions on avoiding cross-contact with allergen-free and allergen-containing materials.

1.4. Product Labeling – Distribution in the United States

1.4.1. All CFF Products shall be properly labeled per the Food Allergy Labeling and Consumer Protection Act of 2004 (FALCPA).

1.4.2. Advisory labeling of CFF allergens is not permitted on Product labels.

1.4.3. The Participant shall have a written policy regarding updates and changes to Product labels that impact ingredient and allergen declarations.

1.5. Product Labeling – Distribution Outside of the United States

1.5.1. The Participant shall provide a list of countries where all CFF Products will be sold.

1.5.1.1. Any regulations outside of the United States shall be researched and met by the Participant.

1.5.1.1.1. The Participant shall use the allergen threshold in the country of sale, or the CFF standard, whichever is lower. The CB and/or MT is not responsible for ensuring Participant's compliance with labeling regulations outside of the United States.

2. Facility

2.1 Personnel

2.1.1 The Participant shall identify and assign a primary contact to work with the CB throughout the duration of the certification process.

2.1.1.1 If the primary contact leaves the Participant's organization or otherwise cannot act as the primary contact any longer, a new primary contact shall immediately be assigned, and the CB be notified.

2.1.2 The Participant shall have an ACP with all protocols and procedures related to allergen management. If CFF gluten is part of the Agreement, this shall also be included in the ACP.

2.1.2.1 The ACP shall also include a copy of the CFF Certification Program scheme and standards, as well as a copy of FALCPA.

2.1.3 The Participant shall provide a current organizational chart that shows all employees who are involved in the production of the CFF Products, and the chain of responsibility throughout the organization. If the Participant utilizes the services from any outside contractors, those shall be included as well.

2.1.4 The CB and/or MT will inform the Participant of any potential conflicts of interest prior to providing certification. If there are any possible threats to the impartiality of the program, those will be thoroughly reviewed and handled by CB and/or MT staff.

2.1.5 The Allergen Control Plan shall require that all employees, visitors and all other outside contractors follow all hygiene requirements to avoid the introduction of an allergen into the Facility. This includes hand washing and clothing requirements, such as smocks or hairnets, to prevent cross-contact of any outside food material.

2.1.6 The Facility shall have a location for employees and visitors to place their personal belongings. This area shall be separated from the manufacturing space by a physical partition.

2.1.6.1 The location shall include posters or other physical reminders of how to avoid bringing allergens back into the manufacturing Facility. This includes the hygiene requirements referenced in 2.1.5.

2.1.7 All personnel who are involved in CFF Product manufacturing shall be trained on food allergies at least once per year. This training shall include an overview of the top 8 allergens, how cross-contact may occur, and how serious it may be if a food allergen is inadvertently added to a CFF Product formulation. The training may be customized with any relevant Participant policies and procedures, such as allergen separation techniques.

2.1.8 The ACP shall be continually reviewed to ensure it is still capturing the manufacturing procedures and personnel currently in use at the facility.

2.1.8.1 The ACP shall also be updated to account for any changes to the CFF Certification Program, or federal allergen labeling regulations.

2.1.9 The Participant shall have an individual or team of individuals who oversee the development, implementation and maintenance of the ACP.

2.2. Receiving and Storage

2.2.1. The ACP shall include procedures for receiving Ingredients and verifying that only approved Ingredients arrived.

2.2.1.1. Quality checks of all incoming Ingredient packages shall also be completed with each shipment. These checks shall be recorded by the responsible employee.

2.2.1.2. There shall be a written procedure for handling a shipment due to an incorrect Ingredient or damaged package.

2.2.1.3. Any employee working in the receiving area shall be properly trained on how to identify allergens in incoming Ingredients.

2.2.2. The ACP shall include a procedure for adequately labeling allergen-containing Ingredients when they arrive, prior to being moved to storage.

2.2.3. The ACP shall include procedures for keeping allergen-containing Ingredients separated from allergen-free Ingredients during intake, storage and movement.

2.3. Allergen Cleaning Program

2.3.1 The ACP shall include Sanitation Standard Operating Procedures (SSOPs) for proper cleaning, sanitizing and maintenance of manufacturing equipment and tools.

2.3.2 The ACP shall include SSOPs for cleaning and sanitizing of the Facility, equipment and tools between the production of an allergen-containing product, and a CFF Product.

2.3.3 The SSOPs shall be validated through an environmental monitoring program.

2.3.4 The ACP shall include a master sanitation schedule.

2.3.5 The ACP shall address how to properly dispose of garbage and waste, as to not introduce an allergen into the manufacturing space.

2.4 Manufacturing

2.4.1 The manufacturing Facility shall be in full compliance with all local and national requirements for the production, packaging and distribution of their Products.

2.4.2 Proper signage shall be posted in the Facility that informs personnel about allergens and gluten (particularly the CFF allergens), and how to avoid cross-contact.

2.4.3 If any changes are made to Product formulation or any CFF allergen is introduced into the Facility, this shall immediately be brought to the attention of the CB to ensure compliance with these standards.

2.4.4 The Facility shall conduct a Food Defense Vulnerability Assessment through the FDA's free Food Defense Plan Builder Program or conduct a similar internal assessment to determine any potential lapses in the security of the Facility.

2.5 Facility Engineering

2.5.1 The Facility shall be designed in a way that enhances the separation of allergen-containing and allergen-free Ingredients and Products.

2.5.2 The Facility shall be aware of any potential airborne allergens and have procedures in place to control the spread as to not come into contact with any CFF Products.

2.5.3 If the Participant utilizes multiple Facilities in the United States for the manufacturing of their CFF Product, each site will need an individual audit and certification. The CFF certification is site-specific for Facilities located in the United States.

2.5.4 If the Participant utilizes one or more Facilities outside of the United States for the manufacturing of their CFF Product, each allergen at each Facility will need an individual certification. The CFF certification is both site-specific and allergen-specific for Facilities located outside of the United States.

2.6 Testing

2.6.1 The ACP shall include a protocol on allergen testing, including training procedures for employees. The protocol needs to include how the kits are ordered, stored, used, and how results are recorded.

2.6.1.1 Any employee involved in the allergen testing process shall be properly trained to ensure testing is being conducted correctly.

2.6.2 Annual competency training shall be conducted for all employees involved in conducting the allergen tests.

2.6.3 The Participant shall only use allergen testing kits or testing laboratories that have been pre-approved by the CB.

2.6.4 Any laboratories being utilized by the Participant shall be ISO 17025 accredited for allergen testing.

2.6.5 The testing method(s) chosen shall be appropriate for the composition of the food, and the item being tested. These considerations shall be documented and presented to the CB as part of the testing approval process.

2.6.6 The testing method(s) must be validated prior to being approved by the CB. This shall be done by using the test on a known allergen-containing sample to ensure it could accurately detect the pertinent allergen(s).

2.6.7 Testing shall be conducted once a month at a minimum for dedicated allergen-free facilities, or up to every Product run depending on the possibility of cross-contact within the Facility.

2.6.8 Test results shall be submitted to the CB in the template provided during the onboarding process. Any deviations from this testing plan shall be pre-approved by the CB prior to implementation.

2.6.9 If the Participant ever receives a positive test result, they shall immediately conduct the test again using a new swab to ensure there was not a false positive. If the second test is negative, a third test shall be used to ensure that it is the correct result.

2.6.10 If the Participant receives two positive test results back-to back, they shall then conduct a root cause analysis to determine the point of failure in the production process.

2.6.10.1 A corrective action shall be implemented to ensure that failure does not occur again.

2.6.10.2 The CB shall be notified within 24 hours of the positive test result and shall also be sent the root cause analysis and corrective actions once they are completed.

2.7 Outbound Shipping

2.7.1 The ACP shall include a protocol for properly staging the outgoing Products in a way that eliminates the possibility of cross-contact. This includes proper labeling of CFF Products and dedicated storage space for CFF Products.

2.7.2 The Facility shall have validated SSOPs for proper cleaning of any spills in the finished Product storage area.

3. Maintenance of CFF Certification

3.1 Use of CFF Seal and Certification Marks

3.1.1 The Participant shall sign a logo use agreement with MT prior to the use of the CFF seals or any other marks of certification.

3.1.2 Only Products that have been fully audited and approved by MenuTrinfo, LLC may use the CFF Seal and Certification Marks.

3.1.2.1 These Products have been identified in the Certification Agreement.

3.1.2.2 Any use of the CFF Seal and Certification Marks follow the branding guidelines laid out by MenuTrinfo, LLC in this manual.

3.1.3 The CFF Seal and Certification Marks shall only list allergens that were included as part of the Certification Agreement. Any additional allergens shall only be added after a secondary audit and certification by the CB.

3.1.4 If the Participant changes their packaging in a way that alters the location, color or placement of the CFF seal or other Certification Marks, it shall be approved by MT prior to going to print.

3.2 Non-Conformities, Root Cause Analyses and Corrective Actions

3.2.1 All major non-conformities must be corrected within thirty (30) days of receipt from the CB. Major non-conformities found in subsequent audits may be grounds for the withdrawal of certification.

3.2.2 All minor non-conformities shall be corrected within sixty (60) days of receipt from the CB. Minor non-conformities found in subsequent audits shall become major non-conformities.

3.2.3 Observations shall be reviewed and either implemented or given written reasoning why changes will not be made. Any observations that have not been addressed may become minor non-conformities at the following surveillance audit.