

“Certified Free From™” by MenuTrinfo® Certification Program Scheme and Standards for Consumer Packaged Goods



Developed and Maintained by MenuTrinfo®, LLC



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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 a Facility. This includes the Major 9 allergens for the CFF certification program.

Allergen: A substance that triggers an immune response.

Major Allergens: In the United States, these are the 9 allergens that make up 90% of the allergic reactions: egg, fish, milk, peanut, crustacean shellfish, soybean, tree nuts, sesame, and wheat. These allergens shall be listed on food labels prominently and in consumer-friendly language. Different countries have different priority allergens that they require to be disclosed.

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. This can occur in the manufacturing process by using contaminated machinery, utensils, shared surfaces, etc. Cross-contact can also occur in the storage, preparation, and packaging 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 9 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.

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

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 Products or Kitchens.

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

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

FSMA - Food Safety Modernization Act

GMP – Good Manufacturing Practices

HACCP – Hazard Analysis Critical Control Points

HARPC - Hazard Analysis and Risk-Based Preventive Controls

MT – MenuTrinfo®, LLC

SOP – Standard Operating Procedure

SSOP - Sanitation Standard Operating Procedures

About MenuTrinfo

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 (now 9) 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.

Disclaimer

This document is for informational purposes only. Following the Certified Free From™ standards for Consumer Packaged Goods will not prevent a food allergic reaction if there are errors made in Ingredient sourcing, 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/HARPC 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.

Background and Introduction

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 and diners who need the safest possible options for themselves or their families and friends.

To develop the Certified Free From™ standards, MenuTrinfo®, LLC used all available resources, starting with the Food Allergy Labeling and Consumer Protection Act of 2004. This important piece of legislation identified the eight (now nine with the passage of the FASTER Act in 2022) most common food allergens and mandated their identification on retail packaged foods. Having standards from the United States Food and Drug Administration allowed for uniform regulations for approving ingredients in CFF Products and Kitchens. Countries outside of the United States may have different lists of major food allergens that require special labeling and consideration in manufacturing. The CFF standards can be applied to any food allergen so long as the standards are being followed.

The Food Safety Modernization Act (FSMA) also brought allergens further into the spotlight in food manufacturing. FSMA categorized allergens as potential hazards in manufacturing, and therefore must be properly controlled to be compliant.

MenuTrinfo®, LLC also has over a decade of experience in the area of food allergies and their proper handling and control. Our work with organizations such as Food Allergy Research and Education (FARE) and Food Allergy and Anaphylaxis Connection Team (FAACT) have given us the necessary recommendations to provide a robust certification program that is strong enough to protect consumers while also being approachable enough for widespread adoption throughout the foodservice industry.

Following a needs assessment put forth by existing MenuTrinfo®, LLC clients as well as interested Participants, the CFF program was developed to fill a void in available food safety certifications. Oversight by an outside Standards Committee and Impartiality Board, and regular review and upkeep of the scheme and standards to ensure a reliable and trustworthy certification that consumers can depend on.

Selection of a CB

The Participant may work directly with MT, or with a CB that is accredited to ISO/IEC 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.
 - b. 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 ANAB-accredited food allergy training course.
- ii. Has completed and passed an ANAB-accredited food safety course at a Food Handler level or higher.

- iii. Has a bachelor's degree or higher in a food safety-related field of study or an equivalent amount of experience in the foodservice industry.
- iv. Has completed the Certified Free From auditor training and has passed the exam.
- v. Has completed the shadow/witness audit schedule as determined by MT.
- vi. Lead auditors for GFSI may be exempted from the normal shadow/witness audit schedule as determined by MT.

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 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:

- iii. Name and address of the Facility or Facilities to be audited.
- iv. Description and overview of Products to be certified.
- v. Description and overview of the Facility and any allergens present
- vi. Allergens to be included as part of the CFF certification.
- vii. Name, phone number and email address of the primary contact

Upon receipt of the application, the CB will review and either accept or decline the certification of the applicant. Applicants may request more information if they are not accepted but must apply again if they would like to try and move forward with certification.

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. 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.

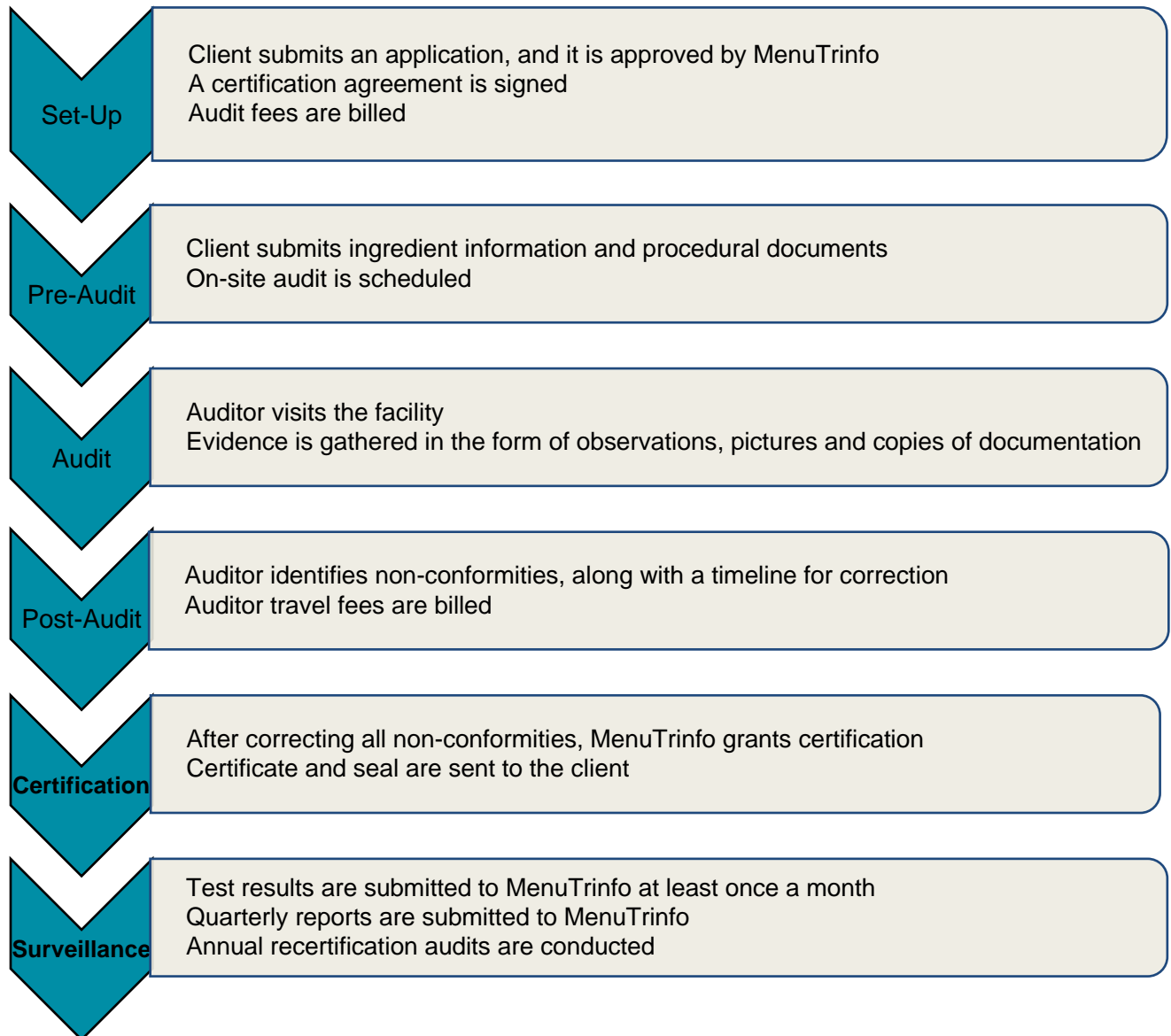
If the Participant elects to include tree nuts as part of the certification, the determination shall be made if that will include coconut or not. MT offers two versions of the CFF seal that include tree nut – one that includes coconut as part of the CFF certification, and one that excludes coconut as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

MT shall have a formal review of the standards, to include a public comment period, during odd numbered years. Major changes to legislation or other normative documents referenced in the CFF scheme and standards may require updates outside of the normal schedule but will be considered case-by-case. Updated scheme and standard documents shall be made available to all stakeholders immediately upon their release, along with necessary guidance on how to implement any changes to certification.

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)

Evaluation

On-Site Audits

Upon execution of the Certification Agreement, an on-site audit will be scheduled. The CB will send an auditor who is trained in the CFF Standards and is also familiar with the industry of the Participant. The CB shall also check for any potential conflicts of interest with the assigned auditor prior to scheduling the onsite assessment. 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/IEC 17065 and those specified by the Certification Scheme.

The on-site audit consists of the following:

- i. Introductory meeting with the auditor and primary contact
- ii. Documentation review
- iii. Guided facility walk-through
- iv. Staff interviews
- v. Closing meeting

During the on-site audit, the auditor may request to take photographs. This is up to the Participant if they allow cell phones/cameras in their facilities, and if they are comfortable with photos being taken. If photos are not allowed to be taken, the auditor can make a written observation in its place.

If the Participant needs to cancel or reschedule an audit, they must let the CB know at least 72 hours in advance of their scheduled audit time. If the Participant does give at least 72 hours' notice to the CB, they will still be billed for the auditor fee, as well as any travel that had already been booked by the auditor.

Non-Conformities

The auditor will 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 could potentially pose a threat to a consumer's wellbeing
- iv. Critical non-conformity: a standard that was not met, and its absence poses an immediate threat to a consumer's wellbeing

The auditor will provide the list of non-conformities to the Participant within five (5) business days from the date of the on-site audit.

All Major and Minor non-conformities shall be corrected within thirty (30) days upon receipt of the evaluation report. Should the Participant require more time than the allotted thirty (30) days, a proposed timeline shall be submitted and reviewed by MT. If accepted, the Participant shall be held to the new timeline for correction.

The steps to resolve a critical non-conformity are as follows:

1. If a critical non-conformity is found during a recertification audit, the Participant's certification will immediately be suspended until the CB has formally approved their corrective and preventative actions as outlined below.
2. If a critical non-conformity is issued during an initial audit, the Participant has ten (10) business days to submit corrective and preventative actions to the CB. This shall include their proposed timeline for correction and re-audit. The CB can accept the plan as written or return with additional requirements.
3. Once the re-audit timeline has been accepted, the Participant must adhere to the dates they've submitted. Rescheduling of the re-audit, except for in cases of extenuating circumstances outside of the Participant's control, shall not be permitted.
4. A re-audit shall be conducted by the CB at least six (6) weeks but no longer than six (6) months after the initial audit. This will be a full audit to ensure successful implementation of all corrective and preventative actions. The Participant shall pay another auditor fee, as well as reimburse travel for the re-audit.
5. If no additional critical non-conformities are found, the Participant shall continue through the remaining steps to certification, including re-issuing a suspended certification or receiving the initial certification.

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 auditor. If the evidence is sufficient, the non-conformity shall be resolved. If the evidence is not sufficient the company shall be notified that it is not acceptable and be asked to submit additional evidence. 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.

The auditor has two (2) business days from the date that all non-conformities have been corrected 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.

Review

The Reviewer shall be an employee of the CB but cannot be the same employee who audited the Participant. The Reviewer shall compare all evidence gathered during the

evaluation and determine if it is enough to meet the CFF standards. This may also include evidence in the form of existing food safety and/or food allergy certifications.

The Reviewer shall then present the information to the Decision Maker.

Certification

The CB shall assign one employee to make the certification decision based on all information gathered during the evaluation, its review, and any other relevant resources. The certification decision shall be carried out by a person that has not been involved in the process for evaluation or review.

Should the decision maker(s) determine that the Participant has passed, 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 results are the property of the Participant and will not be shared with any parties outside of the CB, AB and MT (the scheme owner) without prior permission from the Participant.

A hard copy of the Participant's certification will be sent in the mail if requested, 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. Participant's address
- vii. Facility name (if different than Participant)
- viii. Facility address (if different than Participant)
- ix. Certificate number
- x. Product names included as part of the certification
- xi. CB's name
- xii. CB's address
- xiii. Signatures of authorized officers from MenuTrinfo®, LLC and the CB (if applicable)
- xiv. 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 required testing plan shall be included as a Schedule C addendum to the Certification Agreement. 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. If the Participant fails to submit their monthly testing and quarterly reporting forms on time, it may result in the suspension of their certification and financial penalties as outlined in the Certification Agreement.

Throughout the calendar year, any changes to 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. While every attempt will be made to conduct all initial audits in-person, a virtual/remote audit may be provided for recertifications, as MT deems necessary and/or permissible. The reasons MT may propose a virtual audit are as follows:

- In the event of a global health pandemic or other global/regional crisis that prohibits travel
- If an auditor is not available in the country where the facility is located, so long as none of the allergens in the scope of certification are in the facility
- After three (3) in-person audits of allergen-free facilities, MT and the Participant may mutually agree to conduct remote recertification audits

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 Certification Agreement with MT that includes the proper uses of the logos and seals, per the MT brand identity standards. This must be done prior to using the certification seal or MT name on any Products or marketing materials.

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.

The CFF seal may be used in its original formatting as a black-and-white image or another color that coordinates with the Participant's existing branding. A supplemental branding guide shall be provided by MT upon request by a Participant. Additional formatting and branding considerations may be discussed with MT.

It is not permitted for a Participant to develop their own seal declaring the allergen-free status of their Product(s). The intent of the CFF certification is to give consumers a uniform, easily recognizable seal to look for on the market. Textual statements that do not contradict or otherwise conflict with the CFF seal may be used in tandem.

Testing Requirements

CFF Participants shall conduct chemical testing as a means of validating allergen 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, raw materials and finished goods, based on the individual test, and are simple to interpret correctly, as they are a qualitative method of analysis. Quantitative testing methods, such as Enzyme-Linked ImmunoSorbent Assay (ELISA) or Polymerase Chain Reaction (PCR), are allowed with proper staff training and

knowledge. Outside laboratories may be utilized, as long as the outside lab is ISO/IEC 17025 accredited and allergen testing is part of their scope of accreditation.

Participants shall conduct allergen testing for surfaces, raw materials, and/or finished goods based on the individual facility's operations. A contract addendum shall be executed with each Participant to outline testing expectations. Testing requirements are outlined in the Certified Free From Testing Requirements for Consumer Packaged Goods Supplemental Guidance document.

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, written notification 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
- ix. The Participant's certificate has lapsed by 30 or more days
- x. The Participant is over 30 days late on payment for an audit or auditor travel fees

If a Participant's certification is suspended, they have thirty (30) days to implement any necessary corrective actions. If the event triggering the need for a suspension is serious enough to create a risk to public health and/or safety, the Participant has five (5)

business days to implement the 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 request 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 areas of use, and any certified Products already in the market shall be recalled.

If the Participant recalls 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, anyone involved in the consultation shall not be involved in any of the Evaluation activities for two (2) years.

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: Consumer Packaged Goods

The following standards shall be met by the Participant to qualify for use of the CFF seal for Consumer Packaged Goods. If certification is being sought for a Kitchen environment, the Participant shall consult the Kitchen Standards document.

It is possible that some standards will not apply to certain Participants. In those instances, the standard may be marked as exempt by the auditor along with a qualifying note.

Note: the standards below shall apply to the allergens identified in Schedule A of the Certification Agreement. While allergen best practices should be followed for all major allergens, the certification shall only rely on evidence as it pertains to the Participant's scope of certification.

1. Supply Chain

1.1. Ingredient and Supplier Approval

- 1.1.1. The Participant's Allergen Control Plan (ACP) shall refer to or 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 all Ingredients:
 - 1.1.2.1. The ACP and /or Supplier & Ingredient Approval policy shall contain a procedure to identify and approve Ingredients based on allergen status, including processing aids and food grade lubricants.
 - 1.1.2.2. The process to approve new Ingredients includes evidence that demonstrates that the Participant is thoroughly reviewing any potential for cross-contact prior to approval.
 - 1.1.2.3. Specification sheets and other documents that include adequate allergen information shall be on file for every Ingredient.

1.1.3. The ACP shall refer to or contain a written policy regarding the annual documented verification of the allergen status of all Ingredients used in CFF production.

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 permitted, so long as the Participant follows the same ingredient approval process as demonstrated in 1.1.2.

1.1.5. Fully refined, bleached and deodorized oils from allergenic Ingredients can be used in CFF products, so long as there is proper documentation from the supplier that there are no proteins left in the oil.

1.1.6. Hydrolyzed and fermented ingredients may be approved, so long as documentation can be provided by the supplier stating that all raw ingredients were allergen-free prior to processing.

1.1.7. Distilled ingredients may be approved, so long as documentation can be provided by the supplier stating that all raw ingredients were allergen-free prior to processing.

1.2. Traceability and Recalls

1.2.1. The Participant shall provide a complete list of Products that will be certified. This list shall be maintained by the Participant.

1.2.2. 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.

1.2.3. The ACP shall refer to or describe the recall or traceability plan and shall include a two-way traceability (trace forward and trace backward) process for all Ingredients and Products. Traceability shall also account for any rework material, or waste if applicable.

- 1.2.4. The Facility shall conduct a mock recall at least once per year and maintain records for review.
- 1.2.5. The ACP shall include or refer to 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.

1.3. Product Labeling

- 1.3.1. All CFF Products shall be properly labeled per the Food Allergy Labeling and Consumer Protection Act of 2004 (FALCPA) if they are being distributed within the United States.
 - 1.3.1.1. If CFF Products are being sold outside of the United States, it is the responsibility of the Participant to research all necessary labeling regulations and ensure compliance with each country's laws.
- 1.3.2. Advisory labeling of CFF allergens is not permitted on Product labels.
- 1.3.3. The Participant shall have a written policy regarding updates and changes to Product labels that impact ingredient and allergen declarations.

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.
- 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 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.

2.1.5 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.

2.1.5.1 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.

2.1.6 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 9 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.

2.1.6.1 The allergy training shall include a competency assessment, and results shall be logged.

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

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

2.1.8 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 reference 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 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.

2.5 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 for the manufacturing of their CFF Product, each site will need an individual audit and certification. The CFF certification is site-specific.

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/IEC 17025 accredited for allergen testing.
- 2.6.5 Testing shall adhere to the requirements and schedules identified in the Certified Free From Testing Requirements for Consumer Packaged Goods: Supplemental Guidance document.
- 2.6.6 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.

2.7 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 Certification 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.
- 3.1.5 All packaging with the CFF seal and/or the MT name needs to be submitted to and approved by MT prior to printing.
- 3.1.6 All certified Products must include a copy of the Certified Free From seal, unless exempted by MT due to size restrictions.
- 3.1.7 Alternative icons or seals to portray allergen-free status are not permitted. Textual statements that do not contradict the CFF standards or the Participant's scope of certification can be used.
- 3.1.8 If the Participant chooses to sell the CFF Product(s) in countries outside of the United States, all labeling requirements have been researched to ensure proper use of the seal and marks of certification.

3.2 Non-Conformities, Root Cause Analyses and Corrective Actions

- 3.2.1 All critical non-conformities shall be addressed with the CB within ten (10) business days of the audit, and have all corrective and preventative actions implemented prior to the re-audit. Critical non-conformities found in subsequent audits shall be grounds for immediate withdrawal of certification, with the opportunity to reapply solely up to MT.
- 3.2.2 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.
- 3.2.3 All minor non-conformities shall be corrected within thirty (30) days of receipt from the CB, or have submitted and received approval for an

alternative timeline. Minor non-conformities found in subsequent audits shall become major non-conformities.

- 3.2.4 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.