GFCO Manual

Rev. 2024

The Gluten Free Certification Organization (GFCO) is a program of the Gluten Intolerance Group of North America (GIG)

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Introduction

The Gluten Intolerance Group (GIG), a 501c3 non-profit corporation, owns and operates the Gluten Free Certification Organization (GFCO), as well as all rights to the certification mark displayed on the first page of this document. The GFCO certification mark is the absolute property of the Gluten Intolerance Group and shall not be used by any other person without the express permission of GIG. As the owners and operators of the GFCO gluten-free certification scheme, neither GIG nor GFCO themselves, nor any company they are affiliated with, are involved in the manufacture, sale, or supply of any goods of the kind certified.

The Gluten Intolerance Group released the GFCO Standard rev. 2024 on June 1, 2024, with an effective date of December 1, 2024. The GFCO Standard rev. 2024 replaces the previous GFCO Standard rev. 2020. The Standard gives GIG's requirements for GFCO gluten-free certification.

The GFCO Standard defines the practices required to certify Gluten-Free food products, beverages (both alcoholic and non-alcoholic), nutritionals/supplements, and personal care Products, and to use the GFCO logo on those products.

The GFCO certification body is accredited to ISO/IEC 17065, Requirements for Bodies Certifying Products, Processes, and Services.

This Manual contains the GFCO certification elements that apply to all applicants and certification holders.

Any changes to the policies and requirements in this document will be communicated to all GFCO certification holders with a minimum of 30-day's notice before taking effect.

Suggestions for improvements to this Manual and the GFCO Certification Standard are encouraged from all parties. Send written comments to GIG at 31214 124th Ave. SE, Auburn, WA, 98092, USA.

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Definitions Used in this Manual

Annual: Any activity in the GFCO Certification Standard which is required to be performed on an "annual" basis, or "annually", must be repeated in intervals of 12 months or less. For example, if an initial training occurs in June, that training must be repeated during or before June of the following year to meet the requirement that it be performed annually.

Applicable Gluten-Free Threshold: The allowable upper limit of gluten content in a GFCO-certified Product, as required under the GFCO definition of "Gluten-Free".

Audit Waiver: Waiving the requirement to re-audit a Plant for the purpose of adding the Plant to a Client's GFCO Certification Contract. In the event of an Audit Waiver, an audit report will be produced for the new Client at the next scheduled plant audit.

Brand Owner: A Legal Entity that owns the brand name(s) of the Product(s). The Brand Owner may or may not operate the Plants that make the Product, and may or may not know the identity of the Ingredients used in the Product.

Calendar Quarter: Calendar quarters are defined by GFCO beginning January 1st – March 31st (Quarter 1), and proceeding April 1st – June 30th (Quarter 2), July 1st – September 30th (Quarter 3), and October 1st – December 31st (Quarter 4).

Certification Contract: This is the application level required to certify a Product at any Plant. In any relationship between a Plant and a Brand Owner producing Product, at least one of these entities must have applied for a Certification Contract, and take responsibility for all of the GFCO requirements for Product certification.

Client: A Legal Entity that holds a GFCO Certification Contract as the Brand Owner of GFCO certified Products, or as a Plant manufacturing GFCO certified Products.

Contract Manufacturer: A Brand Owner who has a certified Product made in a Plant that they do not own, and holds a licensing agreement with GFCO to allow the use of the GFCO logo on those products. A Contract Manufacturer may or may not control the ingredients used in the Products, may or may not take responsibility for the finished Product testing requirements, and may have control of other aspects of production as they have arranged with the Plant.

Dedicated Gluten-Free Plant: One in which no part of the Plant, grounds, or storage is used for gluten-containing materials, **OR** one in which the Plant uses some buildings, facilities, or storage for gluten-containing materials BUT the gluten-free production area or system:

- is fully closed off by solid walls and a roof
- has separate entrances from areas used for gluten
- has separate air handling from areas used for gluten

Gluten: The protein fractions of wheat, rye, barley, and their related grains and hybrids that play a role in celiac disease and other gluten sensitivities. This definition also includes oats in those countries that recognize oats as a gluten source.

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Gluten-Free: The presence of Gluten at 10 parts per million ("ppm") or less, or the regulatory threshold of the country of sale, whichever is lower, including a threshold of nil detectable gluten in Australia and New Zealand, AND whole grains, beans, seeds, pulses or legumes that contain less than 0.25 Gluten-containing grains per kilogram.

Ingredient: Any unprocessed raw material made from no more than 2 sub-ingredients (components), in the form that it is received by the Plant. Ingredients are processed or combined in order to make the finished Product. The term Ingredient also includes all commodities, chemicals, and processing aids used when making the finished Product.

Ingredient Risk Factor: A numerical factor of 1, 2, 3, or 4, assigned by GFCO, which is used to define both GFCO's perceived risk of an ingredient as a potential source of gluten contamination, and the expected level of testing of that ingredient prior to its use in any certified Product. See the Definition of Ingredient Risk Levels and Ingredient Testing Requirements sections of this Manual for more information about Ingredient Risk Factors.

Legal Entity: A corporation, joint venture, limited liability company, trust, association or other entity. May also be called a "company".

Licensing Agreement: An agreement that allows a Brand Owner to have their products made with the GFCO certification mark in a Plant that holds its own Certification Contract.

Lot: Any set of products manufactured from the same pull or staging of ingredients, and made on the same production line. For example, if your sausage Plant sets aside 300 lbs. of chicken in refrigeration, and gathers enough seasonings and casings in your room-temperature staging area to run on one line for one or more shifts, all of the sausage produced from that staging of ingredients would be considered one "lot" for the purposes of GFCO testing requirements, even if the sausages go into different package sizes and are labeled with different SKUs or lot numbers. Pulling new ingredients, or using a separate production line, would indicate the start of a different lot. This definition is intended to recognize the risk that occurs at each staging step, for potentially pulling an incorrect ingredient, as well as the potential for different levels of risk on different production lines.

Manufactured Material: Any material used in the production of the Product that, at the time it is received by the Plant, is already composed of 3 or more sub-ingredients or has been substantially processed/modified. An example might be chocolate chips used to make a cookie Product. Another example would be a pre-blended baking or flour mix (cake mix, bread mix, etc.). Manufactured Materials are a type of Ingredient, and must be listed as Ingredients on the Product and Ingredient list along with every sub-ingredient (component) in the material. In general, manufactured materials cannot be certified at the packaging or repackaging stage, and GFCO will need to audit the facility where the manufactured material is made.

Mixed-Use Plant: A Plant that handles gluten without the level of separation described under Dedicated Gluten-Free Plant.

Non-conformance: Any documented deviation from the requirements of the GFCO Certification Standard.

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Plant: A Legal Entity that, in one or more buildings, stores, processes, combines, or packages Ingredients to make a finished Product. The term Plant can encompass a warehouse that receives and stores ingredients, a manufacturing facility, a packaging plant, a finished product storage facility, or any other building that has physical possession of the Product or its Ingredients.

Plant Registration: An annual, required process by which the Plants that make Products provide and update their facility information with GFCO, and confirm that they are aware of current GFCO certification requirements. Plant Registration is a separate process from certification and annual re-certification. Completion of Plant Registration does not confer a certificate, as the GFCO program only certifies Products, not Plants.

Private Label Manufacturer: A Brand Owner who has certified Product made in a Plant that they do not own, and holds a licensing agreement with GFCO to allow the use of the GFCO logo on those products. A Private Label Manufacturer will have no knowledge, control, or responsibility for the Ingredients used to make Products, testing requirements, or other aspects of the Plant's approval to make Products.

Product: Any use of the word product with a capital "P" refers to GFCO certified Product. GFCO certified Products are any items that appear on a valid GFCO certificate and display the GFCO logo.

Publicly Available Products: finished products or raw materials that leave a plant location and are available for sale to any other person or entity, via retail, wholesale, business-to-business, direct-to-consumer, or any other form of purchase.

Publicly Unavailable Products: finished products or raw materials that leave a plant location but are not available for sale to other persons or entities; examples would include unfinished materials (work-in-progress) being transferred to another plant location, promotional/sample products, or finished product lines/brands that have not yet been publicly launched, and are not yet available for sale.

Rental Kitchen: A Rental Kitchen is a Plant that allows multiple manufacturers to pay for the use of the building and its equipment by the hour or by shift, or to rent space for production. Other names for a Rental Kitchen are commissary kitchen or incubator.

Repackaging: A repackaging Plant purchases bulk or pre-packaged goods and re-packages them for sale. Only low-risk Ingredients (level 1 or 2), and not Manufactured Materials, can be repackaged using the GFCO logo. The suitability of repackaged items for certification will be determined during the evaluation of Products & Ingredients.

Supplier: A Legal Entity that provides Ingredients or Manufactured Materials to a Plant or Brand Owner for use in a Product. May also be called a "vendor".

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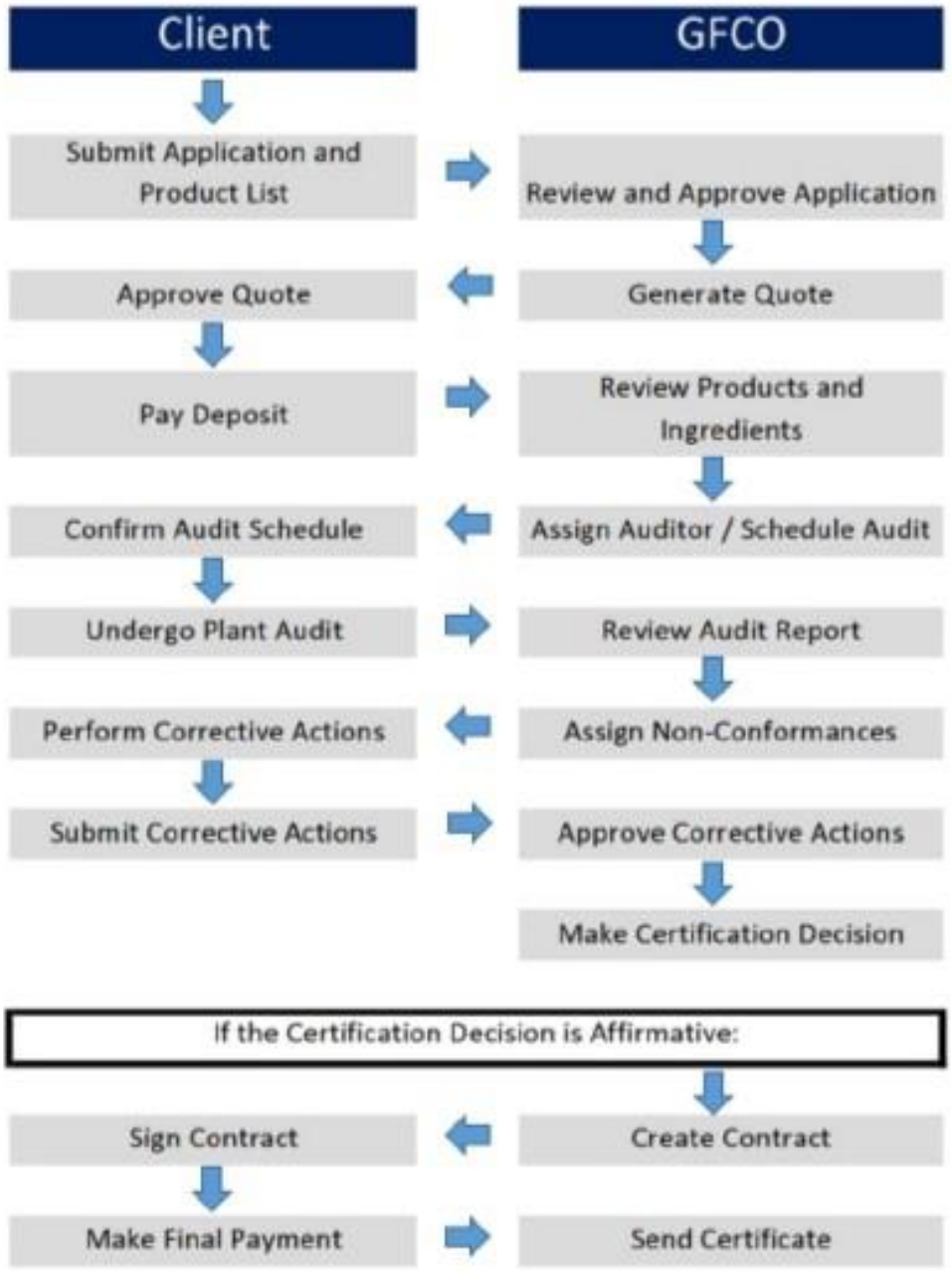
The Certification Process

This flowchart describes the steps for certification.



REMEMBER: No Products can be manufactured with the GFCO logo until you have a GFCO certificate listing those specific Products at the exact Plant where they are made.

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Applying for Certification

GFCO Standard

It is a great idea to learn about the GFCO Standard and safe gluten-free production before applying for product certification. Applicants should familiarize themselves by using this Manual and the GFCO Standard.

Before applying for certification, it is essential that every plant understands the GFCO Standard, and is implementing the Standard requirements.

Register with GFCO

Every Plant that intends to make certified products must register with the GFCO program at www.gfco.org/plant-registration.

Plant Registration may be completed either before or after submitting an application and receiving a quote, but it must be completed before any products or their ingredients can be reviewed, and before any facility audits can be scheduled.

Plant Registration must be renewed annually, and there is a registration fee each year. Plant Registration must be current in order to grant or renew product certifications.

Preparing to Apply for Certification

Before applying for certification, applicants should make sure that their Plants meet all of the requirements of the current GFCO Standard. See the end of this manual for the full text of the Standard, the reasons behind each requirement, and examples of evidence that an auditor might look for.

Before applying, the applicant must also gather information on all of the Ingredients that will be used in certified Products, including information on all of the components in any Manufactured Materials.

Consultancy

The GFCO program does not provide consultancy to applicants or clients beyond the clarification of the Certification Standard requirements. GFCO will never market its activities in conjunction with any organization that offers consultancy. A particular consultancy service will not make the certification process simpler, easier, or faster, or reduce the certification fees.

Certification Scope

GFCO certification can be granted to Products in the categories of Food, Beverages, Nutritionals/Supplements and Personal Care. GFCO certification is specific to a Product made under a specific Brand at a single Plant or set of Plants. Each Plant must comply with the GFCO Standard requirements, including assuring that all Products meet the Applicable Gluten-Free Threshold.

GFCO confines its certification requirements, evaluations, reviews, decisions, and surveillance activities to matters specific to the appropriate Certification Standard and other criteria required for product certification.

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Certification Contracts or Licensing Agreements

In order to certify any Product under the GFCO program, either the Brand Owner or Plant must hold a Certification Contract with GFCO. In instances where the same organization owns both the brand and the manufacturing operation, then that parent organization can submit the Certification Contract application. But if the brand and Plant are under separate ownership, or wish to be considered separate legal entities, then at least one of them needs to apply for and hold a Certification Contract.

If a Brand Owner holds a Certification Contract, they may operate in as many plants as they wish under that contract, whether or not any of those plants hold a Certification Contract of their own. They may also request certification for any and all brands that they own under their contract, and do not need separate contracts for each brand that they own. As spelled out in their Certification Contract, the Brand Owner must be able to guarantee access to the plants to perform the audits, be able to ensure that the plant will address any audit non-conformances, and be able to ensure that they or the plant is addressing all activities required to maintain certification.

If a Plant holds a Certification Contract, it can make certified Products for multiple Brand Owners, as long as those Brand Owners either hold their own Certification Contract or have completed a Licensing Agreement to work in that Plant.

A Licensing Agreement is a contract that allows a Brand Owner other than the Plant holding a Certification Contract to use the GFCO logo on their Products made in that Plant. Licensing Agreements are only available for Brand Owners. A Licensing Agreement can only occur when the Plant(s) manufacturing the product are currently registered with GFCO and have a current Certification Contract issued through GFCO.

The Licensing Agreement provides the Brand Owner with the requirements for the use of the GFCO logo.

New Licensing Agreements can be executed at any time while the Plant is registered and in full compliance with their Certification Contract. The Licensing Agreement application can be submitted by either the Plant or Brand Owner, but it must be signed by the Brand Owner. The fees for Licensing Agreements may be paid by either the Brand Owner or Plant, depending on their own business arrangements.

If a Plant holds a Certification Contract, the Brand Owner will have the option of working in that Plant under either their own Certification Contract or a Licensing Agreement. The following table outlines the differences between the two options.

	Certification Contract	Licensing Agreement
Responsible for payment of certification fees	x	
Responsible for payment of licensing fees*	x	x
Responsible for ensuring that the Plant meets all GFCO Standard requirements	x	
Receives copy of annual audit report	x	
Responsible for updating and managing product and ingredient submissions to GFCO	x	
Responsible for ensuring that testing of ingredients, equipment, and finished products is completed and submitted to GFCO each quarter*	x	x
Responsible for ensuring that all usage of the GFCO certification mark is submitted to GFCO for approval*	x	x

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For responsibilities that may be completed by either a Licensee or Certification Contract holder or shared between them (as indicated by an asterisk* on the table), it is the duty of the Brand Owner and Plant to decide between themselves which party will handle that task. Ultimately, however, the Certification Contract holder is responsible for ensuring that all requirements are met. Failure to meet all certification requirements may result in probation, suspension, or withdrawal of certification, which in turn will result in the withdrawal of all Licensing Agreements that had been allowed under that certification contract.

Because a Certification Contract is required in order for a Brand Owner or Plant to submit Products and Ingredients, and receive a copy of the yearly audit reports, the GFCO program allows both parties to hold a Certification Contract if that is the best business decision for them.

The Certification Applicant

The only Legal Entities that can apply for certification are:

- The Plant that makes the Product and has control over which product packages will bear the GFCO logo
- The Product Brand Owner

Distributors, marketers, or other third parties cannot apply for Product certification. However, they may pay the certification or audit fees for any applicant.

Audited Plants

Prior to certification, every Plant that has any part in manufacturing or packaging the certified Product must be registered with GFCO, undergo an audit, and be approved to manufacture or package certified Products. Each Plant will receive a separate audit and audit report.

Campus Locations

After the initial auditing of each production/packaging site, at the request of the client GFCO may conduct a review to determine if separate Plant addresses can be combined into one location for the purposes of auditing in subsequent years. This type of combined site will be referred to as a Campus location. The primary criteria that GFCO will review to determine if Plants can be combined into a Campus are:

1. Whether the Plants operate under the same management system (policies and procedures).
2. Whether the same plant manager(s) manage the Plants
3. Whether the Plants are close enough together to be considered a Campus (generally within walking distance)
4. Whether the Plants perform identical manufacturing processes, or steps in a continuous process (e.g. manufacturing products in one building that are then packaged in another)
5. Feedback from our auditors on whether the Plants can all be adequately audited within the audit timeline

These criteria will be reviewed internally by a GFCO Manager, who will make a determination on combining the Plant locations under one annual audit.

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In certain cases, GFCO may require that pre-made, multi-component ingredients (Manufactured Materials) are also certified by GFCO, which would entail the addition of the supplier's plant to a certification contract and annual audits of their facilities. See the section below on Product and Ingredient Review for details of when this might be required.

In Rental Kitchens, each Company that wants to make Products must register with GFCO separately, apply for a separate certification, and maintain their own gluten-free policies, procedures, and records. The Rental Kitchen cannot hold a central Plant Registration or certification that applies to other manufacturers working there.

The GFCO Application

GFCO accepts all applications for certification of foods, beverages, nutritionals/supplements, and personal-care items to the GFCO Standard. Consideration for certification does not depend on company size and is independent of other certifications that a Company holds, including other gluten-free certifications. Companies wishing to apply for product certification need to complete the appropriate GFCO Certification Application and a non-disclosure/confidentiality agreement.

The application will require the submission of a complete list of the applicant's proposed Products and their related Ingredients. Please see the next section for more information on this list.

The Company applying for certification must appoint an Authorized Representative who will serve as the primary contact for GFCO. The company must also appoint a secondary Authorized Representative who will be a secondary contact for GFCO.

Once GFCO receives the completed Application and Product & Ingredient List, a review will determine if the Products fall within the GFCO scope of certification.

The submitted GFCO Certification Application and Product List are valid for 6 months. If the applicant does not continue through the certification process within this timeframe, GFCO will confidentially delete these records. The applicant will need to resubmit their information to begin the certification process again.

The Product and Ingredient List

As part of the certification application, GFCO will require each applicant to submit a list of every Product that will be seeking certification and all of the Ingredients that will be used to make those Products. Ingredients are all of the inputs received by the Plant that will be used in the Products, including processing aids, and must be listed exactly as they are received. Products are the materials that leave the plant.

Some Products and Ingredients require additional documentation in order to be approved for certification. Please see the section entitled "Product and Ingredient Review" for more information.

The Products must be identified by UPC code or product number when possible and must be listed by the exact Product name as it appears on any packaging. For Plants that do not make packaged finished goods, the materials that leave the Plant are considered their Products. For example, if a mill obtains quinoa from growers, cleans it, and sells it in bulk totes for further processing, the cleaned quinoa is that Plant's Product.

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The Ingredient list must show all of the components of every multi-component ingredient, and must include processing aids. The Ingredient list for each Plant should reflect the materials that are received by that Plant, in the state they are received. For example, if the Plant receives a pre-blended cookie dough that they subsequently partition and bake, the Ingredient list should list "cookie dough" as the ingredient, with the individual components of the dough listed under "components" – the individual cookie dough components should not be listed as separate ingredients if this is not how the Plant receives them.

The lists must ONLY contain the Products being submitted for certification, and the Ingredients used in those Products, not all of the products and ingredients in the Plant.

This Product and Ingredient list will be subject to review, risking, and approval by GFCO. The applicant will receive a copy of their Product and Ingredient list with risk factors for each ingredient, but this is not evidence of certification approval. Only the receipt of a GFCO Certificate listing the Product(s) at the named manufacturing Plant(s) is evidence that the Product(s) has/have been certified by GFCO.

New Products and Ingredients can be added to the list at any time, which, subject to review and approval by GFCO, will be reflected on an updated certificate. The client will receive a copy of the list with ingredient risks following each submission.

Product and Ingredient Review

The following is a description of what the GFCO staff are looking for when reviewing a Product and Ingredient list, and the types of additional information or documentation they might request in order to approve Products for certification. This list is not exhaustive and certain Products and Ingredients may require additional information not described here. This section also provides information on how ingredient risk levels are assigned.

1. *Matching Products and Ingredients*: The submitted Ingredients must match the Products being considered for certification. For example, if a Product is named "Chocolate Chip Cookies", but there are no chocolate Ingredients submitted, GFCO will request further information.
2. *Repackaging*: If it appears that an Ingredient is being purchased and simply repackaged, GFCO may request additional information. GFCO does not allow high-risk single-component ingredients or Manufactured Materials to be repackaged with the GFCO mark. For single-component ingredients with a risk level of 3 (e.g. chia or buckwheat), GFCO can accept risk reduction documents from the Supplier (GFCO's 3051 form or equivalent) to reduce that risk level to a 2 and allow repackaging. There are exceptions to this requirement for primary grain processors, who receive grains directly from growers, so make sure to indicate whether you are a primary grain processor when you register your plant. Manufactured Materials will always require a GFCO certificate from the Supplier in order to allow repackaging, regardless of the risk levels of their components. Oat Products will also always require a GFCO certificate from the Supplier in order to be repackaged with the GFCO mark.
3. *Manufactured Materials*: If a Manufactured Material is submitted as an Ingredient, GFCO will inquire as to the percentage of that Manufactured Material in the finished Product, by weight, as sold. If a Manufactured Material that is not certified by GFCO makes up greater than 20% of the Product by weight as sold, the Supplier may be required to be a registered

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and approved plant with that material listed on their GFCO certificate. Examples of this might be a frozen spaghetti dinner Product where the applicant buys the gluten-free pasta from a Supplier and lists it as an Ingredient, or a flour blend used to make tortillas. If the Ingredient meets the definition of a Manufactured Material, makes up greater than 20% of the Product by weight, and is high-risk (see Definition of Ingredient Risk Levels below), the Product cannot be certified unless the Plant making the Manufactured Material registered with GFCO and was approved to manufacture by GFCO.

4. *Natural Flavors*: If an ingredient is entered as Natural Flavor, GFCO will request confirmation that the flavor does not contain yeast/yeast extract.
5. *Wheat Starch*: GFCO allows wheat starch in certified products, providing it meets the following requirements:
    a. The wheat starch can't be a "modified" starch, or be enzyme treated or otherwise hydrolyzed as part of its processing, as verified by a statement from the starch supplier.
    b. The wheat starch must consistently test as "not detected" or "below the limit of quantitation", as ELISA methods have been shown to underestimate gluten content in starches. GFCO will request testing data from five recent lots to verify.
    c. In addition to a "Contains" statement on your packaging for wheat as an allergen, you would also have to include a statement that clarifies that the wheat has been processed to allow the food to meet FDA requirements for a gluten-free claim (see the FDA final rule for specifics).
6. *Wheat, Rye or Barley Grass, Juice, Powder, or Fiber:* If these are submitted as a Product or Ingredient, GFCO will request documentation describing how grain contamination is prevented at harvest (for example, do they harvest before the plant produces seeds/grain), how they prevent grain contamination from the seed stock, and how they prevent contamination of stalks or plants collected after the plant produces seeds/grains.
7. *Products Containing Cultures, Enzymes, Yeast, or Probiotics*: Many live organisms are used to produce ingredients and processing aids that are found in gluten-free products. Examples of this are live cultures, bacterially-produced enzymes, yeast extracts, and probiotics. For the safety of gluten-free consumers, and to comply with the FDA final rule on fermented and hydrolyzed products, GFCO needs to confirm that these live organisms were not grown in culture media that contained proteins from wheat, rye, barley, or oats. This can be done using GFCO's 3070 form or equivalent documentation from the supplier. New products cannot be approved if they are made with cultures, yeast, enzymes, or probiotics that were grown on culture media that contained proteins from wheat, rye, barley or oats. As manufacturers are working towards compliance with this new GFCO requirement, GFCO will allow manufacturers up to 6 months to reformulate away from cultures, yeast, enzymes, or probiotics that were grown on culture media that contained proteins from wheat, rye, barley, or oats, in existing certified products. GFCO may also, at its discretion, grant additional time to this 6-month period based on the potential risk to consumers, and the details of the reformulation plan provided by the manufacturer.
8. *Distilled Alcohols Made from Gluten Grains*: Properly performed distillations will remove virtually all proteins, but the facility must maintain records to ensure that each distillation is consistent, and GFCO will request records of recovery volume and ABV from the past 10 production lots in order to approve distilled alcohol Products made from gluten grains (this requirement does not apply to distilled alcohols used in ingredients, such as vanilla

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extract). We would also recommend that the manufacturer contract a laboratory to perform amino acid analysis for residual proteins, to show that their distillation process is effective.

9. *Pre-Packaged Ingredients:* If any ingredients are received pre-packaged from a supplier and will not be re-opened before being included in the Product, such as pre-packed cheese powders for a macaroni and cheese box, or a pre-packed spice blend for a meal kit, all of the components of these pre-packaged ingredients must be low-risk (level 1 or 2). Even with these low-risk components, the pre-packed ingredient will be assigned a risk level of 3, and one pack must be tested from each lot that is received. Any pre-packaged ingredients that contain high-risk components must be certified by GFCO.
10. *Brand Ownership:* If Products are submitted under a brand that is not owned by the certification contract holder, GFCO will reach out to set up a licensing agreement with the owner of the brand.
11. *Assigning Ingredient Risk Levels:* Grain-based ingredients, with few exceptions, are automatically assigned a risk level of 3. Oat ingredients are assigned a risk level of 4. Non-grain-based ingredients are typically assigned a risk of 1 or 2. See the Definition of Ingredient Risk Levels below for additional details on the assignment of ingredient risk. Every lot of an Ingredient with a risk factor of 3 or 4 must be tested prior to use in certified Product. For risk level 3 or 4 ingredients, if the applicant has vendor statements regarding the gluten-free status of the ingredient, proof of ongoing lot-specific gluten testing done by the vendor, or a copy of a vendor's GFCO certificate, they should submit these with the Product & Ingredient list. GFCO can provide a vendor statement template. These documents can reduce the risk of Ingredients and reduce (but not necessarily eliminate) the testing requirements for the Plant.

The Certification Quote

Once the GFCO Certification Application has been reviewed and approved, GFCO can provide a Certification Quote. This quote will serve as an invoice for the required deposit for Certification and as an invoice for the total amount due for a Licensing application. The quote will include the annual certification fee or licensing fee, any annual audit fees, and any estimated fees for audit travel.

The annual certification fee is determined using a standardized fee schedule and takes into account the risk of the Products being submitted for certification. Fees are not based on the number of Products submitted for certification.

The applicant must sign and return the Certification Quote form to GFCO and make the deposit payment before any needed Plant audits can be scheduled. Applicants for licenses will only have a total amount due, and not a deposit. The applicant can mail their payment with a copy of their quote to the GIG main office, or make a payment by credit card. The contact information for making payments is:

GIG Accounting, 31214 124th Ave SE, Auburn, WA 98092, +1 (253) 833-6655

Certification quotes are valid for 30 days and may be amended after this time. Part of the deposit is non-refundable, as outlined in the quote.

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The Audit Process

Pre-Assessment Audits

After submitting an application, the applicant may request a pre-assessment audit to help determine if their management system documentation is ready for the certification audit. For a fee, GFCO will conduct a remote (ICT) evaluation of all applicable management system elements and will report any instances where implementation of the GFCO requirements appears weak, or where a requirement has not been addressed. The findings will be provided in a written pre-assessment report. No formal non-conformance report will be issued, and neither GFCO nor the auditor may offer advice on how to resolve or improve any areas of the management system that are lacking.

Applicants may request only one pre-assessment audit prior to their initial certification. Existing clients are not eligible for pre-assessment audits.

Contact gfco.clientsupport@gluten.org to inquire about a pre-assessment audit.

Certification Audit Scheduling

Once the deposit payment is received and processed for a Certification Contract, any required Plant audits can be scheduled. An audit typically occurs within 8-12 weeks of receipt of the deposit payment and signed quote, and within 6 weeks if a RUSH has been requested and the rush fee has been paid along with the deposit. Rush audit scheduling is only available within the contiguous United States.

It is not required that the Plant be manufacturing Products submitted for certification on the day of the audit. However, the Plant must be fully set up for manufacturing before an audit can be scheduled, with all equipment and lines in place as they will be used to make certified Product.

GFCO will assign the audit to a qualified GFCO auditor, and this auditor will contact the Plant to schedule the audit.

If a Plant needs to cancel or reschedule an audit, they must inform GFCO at least 48 hours before the audit time. The applicant will be billed for the audit and any incurred travel costs if GFCO is not notified of the cancellation at least 48 hours in advance.

Under certain conditions, an audit can be waived at a plant that has been previously audited by GFCO. If a plant is eligible for an audit waiver, a waiver questionnaire will be provided to the plant confirming details related to the production of the applying client's products at that location. If the completed audit waiver questionnaire is approved, GFCO will provide the applying client a Waiver of Audit Report document with the testing requirement frequency for the products at that location. The location can then be added to a GFCO certification contract without the need for an additional audit. At the next scheduled audit at that plant, a full audit report will be provided.

The Certification Audit Agenda

The following are the steps of the GFCO audit, which may occur in any order. The Plant should allow a minimum of three hours for the audit, although it may take longer depending on the complexity of their documents and facility. The Plant should provide the auditor with a location outside of the production area to review documents and make notes after the audit, as well as to hold the introductory and exit meetings.

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1. Introductory Meeting, Discussion of Audit Purpose and Process
2. Document Review. Please be prepared to provide:
    a. SOPs pertaining to gluten-free production.
    b. Current Product and ingredient lists for gluten-free items
    c. Organizational chart
    d. Job descriptions
    e. Purchasing documents
    f. List of approved vendors
    g. Vendor statements on gluten
    h. Training materials
    i. Staff training records
    j. Documentation of receiving inspections
    k. Hazard analysis for gluten
    l. Completed batch/lot records
    m. Documentation of packaging/labeling checks
    n. Corrective action reports for the past year
    o. Mock or actual recall reports for the past year
    p. Internal audit reports for the past year
    q. Testing data for the past year
3. Plant Tour/Inspection
4. Process Observation and Discussion with Staff
5. Documentation of Audit Findings
6. Exit Meeting

During the audit, the auditor may only interact with and obtain responses and evidence from legal representatives and employees of the Plant. It is the Plant's right to have consultants, observers, or other outside parties present at the audit, but these outside parties may not provide evidence to meet audit requirements.

The audit ends once the auditor leaves the facility. If the Plant has additional documentation or evidence they did not present during the audit it should be submitted directly to GFCO in response to any non-conformances.

The Certification Audit Report

The applicant will receive a copy of the audit report within 10 business days of the audit. Annual surveillance reports with be provided within 20 business days. If there are any audit non-conformances, this will be a preliminary report. The report will include all non-conformances as well as any other comments from the auditor and reviewer. An audit report will be prepared for each client holding a Certification Contract in each Plant.

Every audit report will include the testing requirements for the Plant. These are reviewed and updated at each annual audit.

The audit reports are the property of each Certification Contract client, and cannot be distributed to other parties without permission.

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Non-Conformances and Corrective Actions

Following the audit, an internal technical reviewer will review the report. Based on the auditor's findings, the reviewer may determine that the Plant has one or more non-conformances. The audit report will list each non-conformance and identify the relevant requirement from the GFCO Standard. All non-conformances must be addressed within 60 days.

The Plant must address each non-conformance through their corrective action process. Each corrective action must include a description of the problem (this could be the non-conformance as written), an indication of the steps taken to investigate the problem, the determination of a root cause of the non-conformance, and a proposed solution for the root cause. The applicant must submit a corrective action report, along with evidence that the proposed solution has been implemented, for each non-conformance. These documents are reviewed to determine if the non-conformances have been adequately addressed.

Once the applicant has adequately addressed all of the audit non-conformances, a reviewer will go over all of the applicant's documentation, including the application, Product list, and documents received from the audit. This reviewer will make a recommendation for or against certification. This recommendation as well as a statement that all non-conformances have been addressed will be added to the report. A copy of this final report will be sent to the applicant and to the GFCO Program Manager for review in making the certification decision.

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The Certification Decision

The Certification Decision

Following a process check to ensure that all of the required documents for certification are present, complete, and correctly filed, the GFCO Program Manager will review the entire application package and make the certification decision. In the event of an affirmative certification decision, the applicant will be sent a completed GFCO Certification Contract for review and signature.

The Certification Contract

The Certification Contract lists the Plants where certified Products can be manufactured. The Certification Contract must be signed and returned, and the final certification fees, audit fees, and audit travel costs paid before a Product certificate can be generated.

It is the responsibility of the party that signs the Certification Contract to ensure that each of the Plants they use to manufacture certified Product are aware of the requirements for maintaining certification, including but not limited to:

- The GFCO Standard requirements
- Testing requirements
- Submission of corrective actions following audits
- Notifying GFCO of any confirmed positive (greater than the Applicable Gluten-Free Threshold) gluten results in a finished Product.
- Annual Plant Registration

The Certificate

No Product can be sold bearing the GFCO certification logo until the applicant receives a certificate issued by GFCO that lists that specific Product and the GFCO-approved Plant in which it was manufactured. The signed certificate serves as final documentation of an affirmative certification decision.

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Maintaining Certification

There are several conditions that must be met in order to maintain the registration of Plants and the certification of Products. These requirements are reviewed as part of the yearly surveillance audits, and through a review of records submitted directly to GFCO:

- Submission of packaging proofs and other logo use for approval (send to gfco.branding@gluten.org)
- Yearly surveillance facility audits
- Product, Ingredient, and Equipment testing, with data submitted to testing@gluten.org at the end of each quarter.
- Notification of any positive gluten test results in the finished Product, made directly to GFCO at gfco.alerts@gluten.org.
- Annual Plant registration

The failure to meet these requirements may result in the suspension/probation or withdrawal of certification.

Certification is a continuous process and these requirements must be met as long as the Certification Contract is in effect. If a Plant does not want to meet these requirements because they are not in active production, the Plant will need to terminate their Certification Contract, and then re-register and re-apply with GFCO at a later date. There is no “hold” status for certification.

Packaging Approval and Use of the GFCO Logo

The display of the GFCO Logo on any product packaging or print/digital media must be reviewed and approved by GFCO prior to use, by submitting proofs/images to gfco.branding@gluten.org. In addition, product packaging must be reviewed prior to use on certified products to ensure that the packaging does not contain any statements that contradict or negate the GF logo, or might cause confusion for consumers.

When a company applies for certification, they will be provided with a copy of the GFCO Branding Standard. The Branding Standard describes in detail the proper formatting for the GFCO logo. The Branding Standard is also available on the GFCO website.

The applicant will receive logo files for designing their packaging once certification has been granted. By completing a Logo Release Agreement, the applicant may receive these logo files prior to certification in order to begin their packaging design and obtain approval for proofs, but this distribution of the logo does not imply that certification is guaranteed, and GFCO assumes no responsibility for monetary loss if the packaging is designed or printed prior to the issuance of a certificate.

Prior to printing a run of packaging materials, boxes, containers, advertising materials, stickers, or other media, companies must submit the proofs of the print job to gfco.branding@gluten.org. The materials will be reviewed for:

a. Proper layout and sizing of the logo
b. Mention of any components or ingredients that would invalidate the certification claim of the product.

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c. Any other statements or claims that would contradict the use of the GF logo or cause confusion for consumers.

Please note that GFCO does not have the authority or responsibility to approve ingredient lists or any other packaging claims beyond the GFCO logo. If changes are needed in regards to logo use, GFCO will contact the party that submitted the materials to describe the changes and request to see a modified proof. Once the final version is approved, GFCO will notify the company by email and maintain a file of the submitted proofs. Companies who are found to be using unapproved packaging or materials will be contacted by GFCO and depending on the extent of the violation will be given 30-60 days to remove the unapproved materials from the market. Companies found to be using the logo or another logo that violates the trademark of GIG/GFCO will be contacted by the GIG corporate lawyer.

The GFCO logo may only be used on Products that appear on a current certificate issued by GFCO, when manufactured at the Plant indicated on the certificate. The logo may also be used on advertising and promotional materials as long as it is clear that the certification does not apply to the Brand, Plant, any personnel of the company or Plant, or any products that did not appear on a GFCO certificate at the time that they were manufactured.

Surveillance Audits

Each registered Plant is audited at least once per year for compliance with the GFCO Standard. This audit will be identical in scope and content to the initial certification audit and will follow the same agenda. It is not required that the Plant be manufacturing certified Product on the day of the audit, but all equipment and facilities must be set up as they are used for making certified Product.

Surveillance audits are grouped geographically to save travel costs for our clients, so the certification audit is not linked to the date of certification renewal. As long as the annual certification fee is paid prior to the contract renewal date a new certificate can be issued each year, even if the surveillance audit has not yet occurred. No new certificate is issued following the surveillance audit.

The annual surveillance audit of a plant will be assigned to the same calendar quarter in which a previous successful GFCO audit had taken place the year prior.

GFCO will assign the audit to a qualified GFCO auditor, and this auditor will reach out to the Plant to schedule the audit. If the auditor is contacting the Plant to schedule an annual surveillance audit, the auditor will have been provided other supporting sites by GFCO to divide the costs of travel among the group. If the proposed date(s) provided by the auditor for this visit is not viable, the Company may opt to reschedule within the same Calendar Quarter as assigned but may be subject to increased travel based upon an auditor traveling to the Plant independently from the originally assigned group. If the Annual Audit is not completed within the assigned Calendar Quarter, due to a denial or deferral of the audit by the Company or Plant, the Plant may be at risk of removal from the certificate based on the Reduction/Probation/Withdrawal policies listed on pages 32-34 of this manual.

The Company will be responsible for all audit fees and travel costs incurred at a Plant if they have not notified GFCO to remove the Plant from their certification contract prior to the surveillance audit.

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If a Plant needs to cancel or reschedule an audit, they must inform GFCO at least 48 hours before the audit time. The contract holder will be billed for the audit and any incurred travel costs if GFCO is not notified of the cancellation at least 48 hours in advance.

As with the initial certification audit, non-conformances may be assigned based on the findings of the surveillance audit. Non-conformances from a surveillance audit must be addressed within 60 days in order to avoid the suspension, reduction, or withdrawal of certification.

Testing

Products
Each company holding a Product Certification Contract is responsible for ensuring that Product testing is performed as assigned on their annual audit report, and according to the conditions of this Manual. All Plants will be assigned some level of Product testing based on their inherent risks. All testing data, as assigned for ingredients, equipment, and Products, must be submitted to testing@gluten.org at the end of every Calendar Quarter.

The annual audit report will always provide the highest, baseline level of Product testing that is expected from a Plant. Plants that have a documented history of testing with no positive test results in Products have the option of decreasing their Product testing level according to the following schedule. Plants that have a confirmed positive (greater than the Applicable Gluten-Free Threshold) gluten result in any Product should remain at or return to the higher, baseline level of testing described on their most recent audit report. This step-down schedule only applies to Products, and not to Ingredients.

If your assigned Product testing is three times per lot (beginning / middle / end):

- Test 40 consecutive lots at three times per lot (120 tests total). If all results are negative you may step down to:
    - Test 40 consecutive lots, once per lot. If all results are negative you may step down to:
        - Test any one certified Product on 40 consecutive production days. If all results are negative you may step down to:
            - Test any one certified Product during 40 consecutive production weeks. If all results are negative you may step down to:
                - Test any one certified Product during 40 consecutive production months. If all results are negative you may step down to:
                    - Test any one certified Product during each production quarter.

If your assigned Product testing is once per lot:

- Test 40 consecutive lots, once per lot. If all results are negative you may step down to:
    - Test any one certified Product on 40 consecutive production days. If all results are negative you may step down to:
        - Test any one certified Product during 40 consecutive production weeks. If all results are negative you may step down to:
            - Test any one certified Product during 40 consecutive production months. If all results are negative you may step down to:
                - Test any one certified Product during each production quarter.

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If your assigned Product testing is once per day:

- Test any one certified Product on 40 consecutive production days. If all results are negative you may step down to:
    - Test any one certified Product during 40 consecutive production weeks. If all results are negative you may step down to:
        - Test any one certified Product during 40 consecutive production months. If all results are negative you may step down to:
            - Test any one certified Product during each production quarter.

If your assigned Product testing is once per week:

- Test any one certified Product during 40 consecutive production weeks. If all results are negative you may step down to:
    - Test any one certified Product during 40 consecutive production months. If all results are negative you may step down to:
        - Test any one certified Product during each production quarter.

If your assigned Product testing is once per month:

- Test any one certified Product during 40 consecutive production months. If all results are negative you may step down to:
    - Test any one certified Product during each production quarter.

If at any point a Product tests positive for gluten (greater than the Applicable Gluten-Free Threshold), or if the baseline testing assigned following your audit is increased, the plant must return to its most recently assigned testing requirement level and begin this schedule again.

No Plant that manufactures GFCO-certified product(s) may test at a frequency less than once per calendar quarter. The testing levels assigned by GFCO and described here are the minimum level of testing that should be performed, and Plants may choose to perform additional testing based on their own assessment of risk.

Remember that this is a step-down process, and you must complete each step. For example, if your plant is assigned to test 3x/lot, and you make 10 lots of certified product per day, you would reach the first 'step' in four production days, and reduce your testing to once per lot. You would then test 20 additional lots over the next two days in order to reduce your testing to once per day. You would then test on 20 individual production days to reach the next step and reduce to testing once per week. After 20 additional weeks of negative results, you could reduce testing to once per month, and after 20 months you could then reduce to one test per quarter. You could **not** simply test 120 straight lots over a 12-day period and reduce testing to once per quarter. This is all assuming that every test result is negative – if not, you would return to the testing level assigned at your most recent audit.

Visual Examination of Products

In addition to the antibody-based testing discussed above, whole intact grains, seeds, beans, pulses, and legumes that are sold as Products with the GFCO logo must be checked for gluten contamination by visual examination, and meet the threshold of no more than 0.25 gluten-containing-grains per kilogram.

To perform a visual examination, take a minimum of 20 samples from the lot, making sure to collect at least one sample from each container. Use an appropriate sampling tool that will allow

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the collection of material from the top to the bottom of each container, such as a trier, slot sampler, or lance. Reduce each sample to 500g using a Boerner divider, or by coning and quartering. Examine each sample for the presence of wheat, rye, or barley grains, and keep a total count of the number of these grains observed across all 20 samples. Divide the total number of gluten-containing grains seen by 10 (the number of kilograms of Ingredient examined). This number needs to be less than 0.25 for the lot to be acceptable. This means that seeing 2 gluten-containing grains in 10 kg is acceptable, but seeing 3 or more is not.

If you perform a visual examination of these materials as incoming ingredients, you do not need to repeat it for the Product.

Ingredient Testing

All applicants for certification will submit a list of the Products for certification, as well as all of the Ingredients used in those Products. GFCO will assign a risk level to every Ingredient used in the production of certified Products. For any Ingredient with a risk level of 3 or 4, the plant will need to test each lot prior to use (see the Ingredient testing and sampling plans below), or may submit one of the following documents in order to determine if the risk level can be reduced:

- A statement that the ingredient is not harvested, transported, stored or processed with gluten-containing grains, through a facility audit or suitable documentation which must also be available for review by GFCO auditors. A vendor statement template is available from GFCO.
- A copy of the GFCO certificate for the ingredient, also kept on file for review by GFCO auditors.
- Evidence that you receive lot-specific gluten test results (certificates of analysis) from the supplier with each lot of the ingredient received. Also, keep these on file for review by GFCO auditors.

Note that all documents submitted for ingredient approval or risk reduction are considered to be valid until their stated expiration date or for one year from the date they are dated or signed. Undated documents will be considered valid for one year from the date they are submitted. No document submitted for ingredient approval or risk reduction may have an expiration date longer than two years. GFCO will request updated versions of outdated documents in order to continue the approval or risk reduction of ingredients.

<u>Definition of Ingredient Risk Levels</u>

Risk Level 1: These ingredients have no perceived risk for use in gluten-free foods. Ingredients in this category include fats, oils, chemicals, and anything else that does not contain protein.

Risk Level 2: These ingredients have a low risk for use in gluten-free foods. Ingredients in this category include items that may share some part of the supply chain with gluten-containing grains or have had occasional incidents of gluten cross-contamination. Ingredients in this category may also include moderate-risk items that have appropriate vendor testing documentation for each lot, or an attestation that the ingredient is harvested, stored, processed, packaged, and transported with equipment and facilities that do not handle gluten-containing grains.

Risk Level 3: These ingredients have a moderate risk for gluten cross-contamination because they commonly share some part of the supply chain with gluten-containing grains. This category also includes low-risk sealed materials packed at a facility not audited by GFCO that are not opened for manufacturing before being included in the Product (an example is a cheese pouch

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packaged with a macaroni-and-cheese type product). Ingredients in this category may also include high-risk items that have appropriate vendor testing documentation for each lot.

Risk Level 4: These ingredients have a high risk for gluten cross-contamination because they share one or more steps of the supply chain with gluten-containing grains.

Risk Level 5: These ingredients contain gluten proteins from wheat, rye, barley, or related grains, and are prohibited from use in certified Products.

Ingredient Testing Requirements

Risk Level 1: These ingredients do not need to be tested.

Risk Level 2: When used as a minor component in finished products, these ingredients should be tested whenever they are first purchased from a new supplier, or whenever a supplier reports that they have changed their source for the ingredient or one of its components. In these instances, they should be tested at least once prior to use in certified Product. For manufacturers who use Risk Level 2 materials as the sole or major component of their certified Products, these ingredients should be treated as Risk Level 3 ingredients (see below). An example of this would be companies that sell spices or spice blends.

Risk Level 3: For this Risk Level, one random container (tote or pallet of bags for large shipments (> 1000 lb.), or individual bag for small shipments (< 1000 lb.)) from each lot or shipment received must be sampled and tested using a sampling plan validated by the Plant. Please see the section on Ingredient Sampling Plans for the expected minimum level of sampling and testing.

Risk Level 4: For this Risk Level, each container (tote or pallet of bags for large shipments, or individual bags for small shipments) from each lot or shipment received must be sampled and tested using a sampling plan validated by the Plant. Please see the section on Ingredient Sampling Plans for the expected minimum level of sampling and testing.

Shared Equipment Testing

Any Plant using shared equipment for both gluten and gluten-free manufacturing or packaging must maintain records that demonstrate that the cleaning process that followed the gluten-containing production was effective. This can be done by verifying the effectiveness of the cleaning each time it is done, for example by using a GFCO Approved Test Kit or a generic protein swab method (but not an ATP method). Alternatively, the Plant may choose to validate their written testing procedure at least every six months of production.

The following method may be used to validate the written cleaning method used by the Plant. A cleaning method that is validated twice annually using this procedure eliminates the need for gluten or protein swab testing between each gluten-containing and certified gluten-free production run, as long as documentation of the validations is maintained and available for observation by the GFCO auditor:

At least every 6 months, the plant should perform equipment swab testing at three locations following cleaning for the first 5 consecutive changeovers that occur between gluten-containing and certified gluten-free production. This swab testing may be performed using any of the GFCO-approved methods intended for surface swab testing, or a generic protein swab. The cleaning process used must match the cleaning process described in the facility's written procedure, and

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the cleaning should only be done once for each changeover. If all of the swab results from of each of these 5 rounds of testing are negative for the presence of gluten/protein, then the cleaning method can be considered validated and no further swab testing or validation will be required until either:

1. Six months have passed since the last validation. If your facility only produces certified Product during the first or last half of the year (e.g., if you only manufacture for a specific holiday) then you will only perform this validation process once per year.
2. There are changes in the staff that perform cleaning. In this instance, the validation should be re-performed and the data kept as part of the staff's training evaluation records.
3. There are changes in the cleaning procedure. In this instance, the validation should be re-performed and the data kept as validation of the new cleaning method.

In the event that there are positive test results from any of the first 5 rounds of cleaning, we would recommend amending the written procedure (extra wash time/cycles), or documenting additional staff training, and re-performing the validation.

Testing Methods, Documentation and Submission

Testing can only be done using test kits found on the GFCO Approved Kit list. Alternatively, the plant may choose to have testing done by an outside lab that is accredited to ISO 17025 for gluten testing, again using a GFCO-approved method. In either case, test results should be completed and reviewed prior to the release/sale of certified Product.

For equipment swabbing, plants may use a GFCO-approved test kit or a generic protein swab, but not ATP swabs.

Testing records must be submitted to testing@gluten.org at the end of each calendar quarter. Due dates are April 10, July 10, October 10, and January 10 for each preceding quarter. If the Plant does their own testing, they must record their results in a testing log (one is available from GFCO) or other format that provides all of the following information:

- Plant Name: The plant where the Product was manufactured.
- Plant location: The city and state where the plant is located.
- Company/Brand: The Company and Brand Name of the tested Product(s).
- Date: The date the test was performed.
- ID: Internal ID or lot/batch number.
- Description: The name of the item being tested – please list this as it is stated on the GFCO certificate or Product & Ingredient list.
- Item Type: State whether the sample is an ingredient, finished Product or equipment test.
- Testing Method: List the test kit used as well as the kit's lot number and expiration date.
- Result: Given as Positive/Negative, < or >, or an exact value.
- The identity of the technician performing the test.
- Any action taken if the test result was greater than the Applicable Gluten-Free Threshold.

Pictures of test strips are not required for documentation. Test results from outside laboratories should include all of the information above.

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Notification of Out-of-Specification Product and Recalls

The registered Plant or Brand Owner must notify GFCO at gfco.alerts@gluten.org immediately in the event of a confirmed positive gluten result (greater than the Applicable Gluten-Free Threshold) in any Product. This allows GFCO to assist with the corrective action investigation, and to determine if there are any circumstances (such as testing failures) that might allow the Product to be released.

The general process for following up on a positive is as follows:

1. When a manufacturer obtains a positive result in a certified finished product, they should perform a second test.
2. If the result of that second test is also positive, they should contact GFCO and quarantine/hold the product. The plant should then send out 6 additional samples to a 3rd party ISO 17025 accredited laboratory for quantitative testing using a GFCO-approved method. These samples should be taken as 6 separate samples or intact packages, randomly spread throughout the lot.
3. If the second test is negative, the facility should perform 5 additional tests on different product packages (the plant can use its own in-house method for this testing). If the results of all of these are negative, the facility should document the testing and investigate possible reasons for the initial positive result, and the product can be released with the GFCO logo. But if any are positive, the plant should send 6 samples out to a lab as described above under point 2.
4. Once the test results are back from the lab, GFCO will work with the manufacturer to make a product release decision:
    a. If all of the third-party lab results are greater than the Applicable Gluten-Free Threshold, the manufacturer will need to recall all packages of that product lot that may have been released to distributors and retail locations. The lot cannot be released or sold with the GFCO logo.
    b. If the results from the additional tests are above and below the Applicable Gluten-Free Threshold, then we will determine the mean plus two standard deviations. If that value is less than the Applicable Gluten-Free Threshold the manufacturer can release the lot, but if that value is greater than the Applicable Gluten-Free Threshold, the manufacturer will need to recall all packages of that product lot that may have been released to distributors and retail locations. The lot cannot be released or sold with the GFCO logo.
    c. If all of the 3rd party lab results are below the Applicable Gluten-Free Threshold, GFCO will review the method used to obtain the initial positive results and make a determination regarding product release.

GFCO must also be notified, at gfco.alerts@gluten.org, before or as part of any withdrawal or recall of certified Product.

Proficiency Testing

Requirement 72 in the GFCO Certification Standard requires facilities that perform in-house gluten testing to participate in a Proficiency Testing scheme for gluten at least every 4 years. Proficiency Testing, or PT, is a requirement that allows GFCO and manufacturers to verify that

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gluten tests are being performed and reported correctly. Proficiency Testing can also serve as a comparison of kit performance across multiple testing sites.

In Proficiency Testing, a Plant signs up to receive a set of unknown samples, which they will test for gluten using their normal test method. Portions of these same samples will also be sent to other facilities that sign up for this same PT "round". All PT participants receive detailed instructions about how to treat the samples and report their results. A deadline is set for result submissions, and as each participant submits their results they will be given a unique, de-identified participant number. Once all of the results have been analyzed and compiled, every participant will receive a report that reveals the gluten content of each of the test samples and the results by participant number. If enough data is available, the results can also be broken down by test method.

GFCO will offer a PT round each year, with sign-ups from January 1st to November 30th at www.gluten.org/proficiency-registration. Samples will be shipped as sign-ups are received, and preliminary reports will be issued within 2 weeks of result submission. The final date for result submission will be December 31, and a final report will be issued in January of the following year. There are other organizations that offer gluten PT rounds commercially — FAPAS (www.fapas.com) in the United Kingdom, and Bipea (www.bipea.org) in Spain are two examples, and their programs are accredited by ISO. Additionally, some test kit manufacturers offer check samples for the users of their test kits. All of these programs are suitable for meeting the GFCO Standard requirement.

Plants must also meet requirements 72 and 74 of the GFCO Standard by having a written policy that states that they will participate in PT for gluten at least every 4 years, and will complete a Corrective Action investigation for any incorrect PT results.

Plants that do all of their testing with outside laboratories do not have to participate in PT.

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Changes to the Certification

Contact Information Changes
GFCO must be notified of any changes to the contact information for the Plant's primary or deputy authorized representatives, for the Brand Owner's primary contact, or for any company's accounts payable contact. GFCO must also be notified of changes in company ownership, company name, or company business address.

Adding or Relocating Plants
New Plants must complete a separate registration, and apply for approval through GFCO.

A change in plant location voids the current certification, and the new location will need to register and apply for approval with GFCO.

Removing Plants
GFCO must be notified immediately in the event that a Brand Owner will no longer be making certified Products in a Plant**.** The Plant must also notify GFCO if they wish to terminate their plant registration. GFCO is not responsible for audit fees or travel costs for any audit performed at a facility that the company is no longer using if the company has not notified GFCO in advance of the change. However, notifying GFCO far in advance of a Brand Owner's plan to stop using a Plant does not exempt the Brand Owner or Plant from any audits that are performed while that Brand Owner is still operating in the Plant, regardless of how soon after they intend to stop having Product made there.

The Plant must immediately cease the use of the GFCO logo on any Brand Owner Products, as of the date the Brand Owner has provided to GFCO. GFCO has the right to request proof that the use of the logo has been discontinued.

Changing Ownership
GFCO must be notified of all changes in the ownership of a Plant or Brand within 30 days of the event.

If a Plant changes ownership but maintains its same legal name and Plant location, the Plant can maintain its registration and certification status.

If the change in ownership results in a change in legal name, the Plant will need to re-register and address the changes with GFCO.

If the change in ownership results in a change in manufacturing location, the Plant will need to re-register and submit a new application to GFCO.

Product Removals and Additions
During the period that a Plant or Brand Owner holds a valid Certification Contract, they may add or remove Products from the certificate by submitting an updated list of Products to GFCO. The Product and Ingredient list amendments will be reviewed within 10 business days, and GFCO will provide a new certificate that reflects the approved changes.

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Each company holding a certification contract is responsible for maintaining their own records of the Products and Ingredients that have been submitted for GFCO certification. For confidentiality reasons, GFCO cannot provide any party with a list of the Products and Ingredients that we have on file. Updated Product and Ingredient lists and certificates can only be returned to the authorized contacts.

Changing the Certification Term

The term of each Certification and Licensing contract with GFCO is 12 months. Once the licensing or certification fee has been paid for the term, that fee cannot be prorated if the client chooses to terminate before the end of the contract term. However, clients who wish to renew their certification for a term that is less than 12 months may do so by contacting their Account Representative.

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General Policies

International Use of the GFCO Logo

The GFCO logo may be used on Products sold in any country.

Any Products manufactured, produced, packaged, or sold in any country must additionally be in compliance with such standards as applicable to such country as well as remain in compliance with the Certification Standard. For example, and without limitation, Products in Switzerland must adhere to and at all times be in compliance with the Guarantee Mark Standards applicable to Switzerland, as well as remain in compliance with the Certification Standard. To the extent it is impossible for a Product to remain in compliance with both the Certification Standard and the country-specific standard, it shall not be deemed a default for a Product to fail to meet the Certification Standard so long as such Product is in compliance with the country-specific standard.

Requirements 3 and 12 of the GFCO Standard describe the responsibility of the Brand Owner and/or manufacturing Plant to be aware of the labeling requirements for each country where the product is sold. One common example is the requirement to use specially produced or processed oats in products labeled gluten-free in Canada, and to label those oats as “gluten-free oats” whenever they are mentioned on the packaging; another is the ban on oats in products labeled gluten-free in Australia, New Zealand, and South Korea. Companies should work with their distributors to ensure that product labeling is meeting the requirements of each country of sale.

Outsourcing

The only certification activity that might be outsourced by GFCO is the performance of Plant audits by external Auditing Bodies.

GFCO outsources auditing services to organizations that meet the applicable requirements of ISO 17021-1, as defined by the GFCO scheme. Accreditation to ISO 17021-1 will be accepted as meeting these requirements – otherwise, Auditing Bodies will be audited to these standards before working with GFCO, and every 2 years thereafter. All auditing bodies will be reviewed for the applicable contract requirements, adherence to 17021-1, and through internal feedback, every 2 years.

GFCO takes responsibility for all activities outsourced to these external Auditing Bodies and will notify clients in advance if an external Auditing Body is to be used.

GFCO retains all authority and responsibility for the certification decision.

Public Information

GFCO maintains publicly available lists of approved Plants and Certified Products.

Any Plant that holds an active Certification Contract will appear on the GFCO Manufacturer Listing, unless the plant has indicated, at the time of registration, that they do not wish to appear on the public list. The information on the public Plant list may include:

- Plant Name
- Plant City
- Plant State
- Plant website (if provided)

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- Plant availability for co-manufacturing (if indicated)
- Plant status (approved, probation, suspended, withdrawn, terminated)
- Expiration date of plant approval

To request that Plant information be removed from the public list, contact GFCO via email at gfco.clientsupport@gluten.org.

All Publicly Available Products that appear on a current valid GFCO certificate will appear on the GFCO Certified Product list. The information on the public Product list may include:

- Product Category
- Product UPC (if available)
- Product Brand
- Product Name
- Expiration date of Product certification

Auditor Qualifications

Prospective auditors must meet the following requirements to serve as a contract auditor for the GFCO product certification program:

- A minimum of 2 years' experience in a food safety, quality, regulatory or auditing environment.
- Successful completion of auditor training to the GFCO certification standard.

All new and current auditors participate in the annual GFCO Auditor Training. This training is conducted either in-person or online. This training will include:

- Auditor Performance Requirements
- Auditor Safety Requirements
- The GFCO Auditing Process
- Detailed Training on the GFCO Standard

This training will include an evaluation, and only those trainees who successfully complete the training and evaluation will be approved to conduct GFCO audits.

In addition, new auditors who are not approved as lead auditors for a GFSI-recognized scheme will have to successfully complete a minimum of two shadow audits, one as an observer and a subsequent one as a lead auditor, to be approved to conduct GFCO audits. Auditors who are GFSI lead auditors will need to be observed performing at least one GFCO audit prior to being approved to conduct GFCO audits independently.

All auditors may also be asked to complete online refresher trainings assigned by GFCO, in between the annual trainings. These refresher trainings will also include an evaluation. The results of all training evaluations must be considered in an annual Auditor Review Process.

All auditors are expected to meet GFCO's requirements for accepting audit assignments and completing and submitting audit reports.

Auditors are also expected to meet basic requirements for professionalism, impartiality and confidentiality. These include:

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- An auditor may not audit a company or a plant owned by a company by whom they have been previously employed, or to whom they have provided consulting in regards to the GFCO Standard, in the past 2 years, and must notify GFCO immediately if they have been assigned to do so.
- The auditor should notify GFCO if there could be any perceived lack of impartiality on the part of the auditor, and be prepared to be removed from the audit assignment. This could occur if:
    - The auditor is assigned to a plant owned by a previous employer or by a competitor of the auditor's previous employer.
    - The auditor is related to or has a friendship or other relationship, positive or negative, with an employee of the company or plant being audited.
    - The auditor has any other relationship with the plant, its parent company, or affiliated organizations that might impact the auditor's ability to conduct an impartial audit or might be perceived as affecting the auditor's judgment.
- The auditor must give each client sufficient notice when scheduling an audit. Auditors should contact the company/plant at least two weeks prior to the proposed audit date.
- The auditor should respond promptly (within 48 hours) to any communications from GFCO or its clients.
- The auditor must dress appropriately for the audit (see safety requirements below).
- The auditor must follow all confidentiality requirements imposed by the company/plant being certified, including restrictions on taking photos or removing documents from the audit site.
- The auditor should fill out the audit forms completely and provide as much information as possible – avoiding yes/no answers, and not leaving any areas blank.
- The auditor may not offer consultation to a client that they are auditing, but they may offer suggestions or possible solutions that they have knowledge of.
- The auditor may not discuss any other certified company, by name or inference, with the company being audited.

Auditor Safety Requirements

GFCO audits take place in manufacturing environments. All GFCO auditors must observe the following minimum requirements for safety in addition to any specific safety requirements imposed by the company/plant that is being audited.

- Wear non-porous (not cloth or leather), skid-resistant boots or high-top shoes. Plant floors are often washed down and the auditor may need to walk through 1-2" of water. The auditor may also be asked to use a shoe bath or have their shoes decontaminated using foam or liquids.
- Do not wear any jewelry, make-up, or nail polish to the Plant.
- If you bring a clipboard or pen into the Plant, make sure they are metal (stainless steel) and washable. Foreign body contamination is a large concern and if a pen or clipboard is dropped the Plant will want to be able to find it with their metal detector.
- In general, the auditor should only walk into the Plant where they have been directed by the Plant representative. The auditor should ask permission before walking around any Plant areas, particularly around production lines or anywhere there is equipment or moving vehicles such as forklifts.

Auditor Evaluation

GFCO will conduct and maintain records of regular auditor evaluations.

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Reduction, Probation, Withdrawal or Termination of Certification

Reduction is the removal, by GFCO, of Products or manufacturing Plants from a certification. This differs from Product updates submitted by the Company, in which Products may be removed at the Company's request, or the voluntary addition or removal of manufacturing Plants.

The removal of Products from the GFCO certificate may occur because:

- The Products were approved in error.
- An ingredient change in the Product has made it ineligible for certification.
- The Products were misrepresented at the time they were submitted for certification.
- Additional information obtained by GFCO has made the Product ineligible for certification.

The removal of Plants from the GFCO certificate may occur because:

- The Plant refuses to allow GFCO auditors to complete an audit.
- The Plant does not complete an annual surveillance audit in the Calendar Quarter assigned.
- The Plant refuses to meet the GFCO Standard requirements.
- The Plant does not complete corrective actions following an audit within 60 days.
- The Plant does not comply with the testing requirements as listed in the certification contract.
- The Plant is found to be using the GFCO logo incorrectly and does not remedy the violation within the timeframe requested by GFCO.

In the event that any of these situations arise, the GFCO will notify the Company in writing or via email of the intent to reduce their certification. The Company will have 30 days to respond and supply additional information to appeal the reduction. These additional materials will be reviewed and the final decision for reduction will be communicated to the Company within 10 days of receipt of the additional materials. If the decision to reduce the certification stands, the company will be supplied with an updated certificate that no longer contains the Product(s) and/or Plant(s) being removed. The GFCO database and online product list will be updated to reflect the reduced certification.

Probation is a certification status in which the Company has not met its contractual requirements, and has been given a period of time to meet its obligations to avert Withdrawal of certification.

GFCO will place a certification on Probation if:

- The client's only Plant, or all of their Plants refuse to allow GFCO auditors to complete an audit.
- The client's only Plant, or all of their Plants do not complete an annual surveillance audit in the Calendar Quarter that Plant is assigned.
- The client's only Plant, or all of their Plants, refuse to meet the GFCO Standard requirements.
- The client's only Plant, or all of their Plants, do not complete corrective actions following an audit within 60 days.
- The client's only Plant, or all of their Plants, do not comply with the testing requirements as listed in the certification contract.
- The client's only Plant, or all of their Plants, are found to be using the GFCO logo incorrectly and does not remedy the violation within the timeframe requested by GFCO.
- The client has a second documented instance of improper logo use.

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In the event that any of these situations arise, GFCO will notify the Company in writing or via email of the intent to place their certification on Probation. The Company will have 30 days to respond and supply additional information to address the compliance issues. These additional materials will be reviewed and the final decision for Probation will be communicated to the Company within 30 days of receipt of the additional materials. If the Probation decision stands, the GFCO will immediately change the affected Plant's registration status to reflect the Probation.

Once on Probation, the client will have an additional 30 days to address the compliance issues before their certification is moved to Withdrawal. If the corrective action has been implemented successfully, GFCO will immediately amend the Plant's registration status.

Withdrawal is the cancellation of the certification contract by GFCO and the withdrawal of all rights for use of the GFCO certificate and logo.

Withdrawal of Certification is a serious step and will be initiated only when it becomes apparent that normal corrective action proceedings, including Probation, have been unsuccessful in bringing about full compliance with the GFCO Certification requirements.

GFCO will move to withdraw certification when the Company:

- Is notified of a Probation but does not address their compliance issues within 30 days.
- Has falsified records or otherwise mislead GFCO
- Fails to meet its financial obligations
- Has a change of name or location – these require a new registration and application for certification
- Has a third documented instance of misuse of the GFCO logo.
- Presents an immediate public health risk to consumers.

In the event of a potential withdrawal, GFCO will notify the client in writing or via email, including the reasoning and the effective date.

If the withdrawal is due to non-payment, once the client is 60 days past-due they will be sent a withdrawal warning, and given an additional 30 days to make their account current. At the end of those 30 days, GFCO will notify the client and any other Brand Owners or clients whose certified Products are affected by the withdrawal. Following this final withdrawal notice, Products can be made at these facilities for an additional 30 days before the Plants' statuses will be changed to "withdrawn" and the Products removed from the GFCO list of certified Products

GFCO allows a standard time-frame of 30 days to respond and resolve the notice of Withdrawal, with the only exception being, in the event a process or certified product is discovered to present a public health/safety risk, GFCO will require response and resolution within 10 days.

If the withdrawal is due to a lack of compliance with GFCO requirements, GFCO will notify the client of the compliance issues and attempt to assist the client in resolving them. If the client is non-responsive within the time-frame provided in the notification, or if the client indicates that they are unwilling to comply with GFCO requirements, the withdrawal will be immediate, and include the removal of all associated products from the GFCO list of certified Products, the change of the Plants' status to "withdrawn", and the notification of all Brand Owners and other clients whose Products are affected by the withdrawal.

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If a client's certification is withdrawn, they will need to re-register and re-apply for certification after addressing the financial or compliance issues that led to the withdrawal. Depending on the reason for the withdrawal, GFCO may impose a "waiting period" of up to 6 months before the client may re-apply.

If a client re-applies for certification after a "waiting period," GFCO's review of such application shall include consideration of the reasons of the certification withdrawal and the client's historical practices. GFCO reserves the right to reject any application for certification if GFCO determines that a client's prior history demonstrates a disregard of public safety, a disregard of GFCO's certification standards and policies, or otherwise poses a risk of noncompliance with the same going forward.

Following notification of Withdrawal, the Company will still be responsible for payment for all services rendered (audits, travel fees) and fees under the certification contract.

Termination is the term used when a company wishes to voluntarily withdraw from the certification program.

Termination must be done by written or email notice to GFCO. The termination date will be the expiration date of the current, active certificate(s) held by the client. All Brand Owners or other clients whose Products will be affected by the termination will be notified of the pending termination no later than 30 days before the certification term ends, or immediately if the remaining certification term is less than 30 days.

In the event that any Certification Contract has been withdrawn or terminated, GFCO will notify any clients holding a Licensing Agreement at the affected Plants, and those Licensing Agreements will be considered terminated as of the date of the Plant's certification withdrawal or termination.

The Use of Information and Communications Technology (ICT) in GFCO Certification

Definitions

ICT: Per the International Accreditation Forum (IAF), Information and Communications Technology (ICT) is defined as "the use of technology for gathering, storing, retrieving, processing, analyzing and transmitting information. It includes software and hardware such as smartphones, handheld devices, laptop computers, desktop computers, drones, video cameras, wearable technology, artificial intelligence, and others. The use of ICT may be appropriate for auditing/assessment both locally and remotely."

Onsite: Corporeally present at the facility that is being audited, with the ability to physically access, observe, and interact with all objects, areas, and personnel within the facility necessary to complete the audit.

Remote: Observing and interacting solely through the use of an ICT device.

ICT Minimum Requirements

1. The equipment used for ICT must be of sufficient quality and capability to allow remote auditors, observers and evaluators to adequately visualize conditions in the plant, including the review of document contents. The audio capabilities must be sufficient for remote auditors, observers and evaluators to hear comments from all persons participating in the audit, as well as activities in the plant.

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2. ICT equipment must be acceptable to the plant for use in all production, packaging, storage, and office areas.
3. It is the responsibility of the certification body/auditing body to confirm that their equipment is acceptable for use throughout the plant and to confirm that the plant's infrastructure can support the ICT being proposed.
4. It is the responsibility of the certification body/auditing body to maintain documentation of the client's approval of any use of ICT.
5. It is the responsibility of the certification body/auditing body to set policies regarding the confidentiality of any information gathered or transmitted via ICT, and to inform the client of these policies.
6. The certification body/auditing body must account for any potential increases in the time to perform audits, assessments, evaluations, or observations, and make the client aware of these additional time requirements when requesting their approval to use ICT.
7. It is the certification body's/auditing body's responsibility to ensure that all auditors and necessary staff understand and are competent in the use of the designated ICT, and in utilizing and maintaining the confidentiality of, the information obtained through ICT.
8. Any audits, assessments, evaluations, or observations done using ICT shall clearly state the extent to which ICT was used, and include an assessment of the effectiveness of ICT in achieving the desired objectives.
9. All certification body/auditing body policies and procedures involving the use of ICT must address all requirements (Section 4) of IAF MD 4:2018

<u>Use of ICT for performing initial/new client audits</u>

New client certifications cannot be granted without an onsite audit. However, the onsite portion of an initial/new client audit may be addressed through an ICT-aided "hybrid" audit, to allow greater flexibility in auditor assignment. This would work specifically as follows:

- Any auditor that is trained and approved by the certification body/auditing body as a lead auditor under the current iteration of a GFSI-recognized food safety standard that covers packaged foods (FSC 22000, SQF, BRC Global Standard for Food Safety, or IFS) may serve as the onsite observer for the new client audit.
- The certification body/auditing body will assign a fully-trained and approved GFCO auditor to direct the audit and guide the onsite auditor remotely using ICT. The GFCO audit form will be completed by the trained and approved GFCO auditor.
- The onsite auditor must directly observe, and demonstrate for the remote auditor, each of the requirements audited under the "Sanitation and GMP", "Processing", "Testing", "Products and Ingredients" and "Mixed Use/Shared Equipment" sections of the 3010 – GFCO Audit Form Template. The onsite auditor may independently verify the requirements covered under the "Plant Management System" section of the audit form template, and provide references for the evidence they observed to the remote GFCO auditor.
- Approval for the use of ICT, and this "hybrid" audit model, must be obtained from the client prior to the audit, and this approval must be recorded by the certification body.
- Other than the observations made under the "Plant Management System" section of the audit form, the onsite and remote portions of the audit must be performed simultaneously, with a live feed from the onsite auditor to the remote auditor.

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Use of ICT for performing surveillance/renewal audits

In extreme circumstances where travel restrictions, acts of god, or threats to auditor health and safety prevent an onsite audit, and options for a certificate extension have been exhausted, a renewal/surveillance audit may be conducted completely remotely, with the use of ICT. The criteria that need to be met and documented for any client to receive a fully remote audit in place of their annual on-site audit are:

- Demonstration that there is no possibility of an on-site audit, including the reason why (must be extreme circumstance, not simply for client or auditor convenience);
- The client must be in good standing with the certification body, current on testing submissions, proficiency testing and label approvals, and provide documented acceptance of a fully remote audit
- The audit report generated from a remote audit must clearly state that the audit was performed remotely, and include the justification for this decision.
- The certification body/auditing body must maintain records of their justification and risk assessment.
- All certification bodies/auditing bodies must continually evaluate their ability to perform on-site audits for clients who have received a fully remote audit and perform a “hybrid” or on-site audit as soon as possible.
- There may never be two back-to-back (consecutive years) fully remote audits of any facility.
- For any facility receiving a remote audit that is not dedicated to gluten-free production, the facility must be directed to perform Product testing at a minimum of one test per production lot of certified Product until such time as they are audited in person, regardless of other risk factors that might result in a lower level of testing, such as a lack of shared equipment or the GFCO step-down schedule.

Alternatively, a “hybrid” renewal audit may be performed as described above under “**Use of ICT for performing initial/new client audits”.**

Use of ICT for approving auditors

Auditors that have completed GFCO Auditor Training, either online or in-person, and that are already approved by the certification body/auditing body as lead auditors under the current iteration of a GFSI-recognized food safety standard that covers packaged foods (FSC 22000, SQF, BRC Global Standard for Food Safety, or IFS), may be observed for their ‘shadow audit’ via ICT. This would operate according to the “hybrid” audit described above, with the trained GFCO evaluator observing remotely, but with the following differences:

- The onsite auditor being shadowed would direct the audit; the remote auditor would simply observe, evaluate, and step in where necessary.
- The onsite auditor being shadowed would complete all sections of the audit form.

The certification body/auditing body would then use their normal criteria for assessing the auditor’s performance and report, and for making their decision on approving the auditor as a GFCO auditor.

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Auditors who are not already approved by the certification body/auditing body as lead auditors for one of the mentioned GFSI-recognized schemes require two shadow audits before being approved as a GFCO auditor. Only one, but not both, of these shadow audits may be observed using ICT. The certification body/auditing body may decide which audit they would prefer to observe remotely.

Use of ICT for evaluating auditor performance
Certification bodies/auditing bodies may use ICT for performing regular GFCO auditor evaluations. The ICT remote observation must encompass the entire audit.

Use of ICT for verification of corrective actions
In instances where plant observation is needed to confirm that a corrective action has been implemented for any non-conformance with GFCO certification requirements, ICT may be used to make those observations.

Use of ICT for evaluating Brand Owner requirements
The GFCO Scheme may use ICT to evaluate compliance with Standard requirements 1-10, which are not covered during the plant audits.

Conflict of Interest

The certification of Products requires that the practices of GFCO be fair and impartial to all applicants for certification. GFCO evaluates certification applicants based solely on their Products and production practices and does not allow any other information to affect a certification decision.

For the GFCO certification program, employees and auditors will be considered to have a potential conflict of interest if:

- They were employed by a registered Plant or their direct competitor, or performed consulting work in regards to the GFCO Standard for the Plant, within the past 2 years. This means they cannot work with or make decisions regarding certification for these Plants, but may work with others where no conflict exists.
- They have a relationship, positive or negative, with anyone working in a registered Plant. This means they cannot work with or make decisions regarding certification for this Plant, but may work with others where no conflict exists.
- They or their family have a financial interest in any of our registered Plants (direct ownership, individual stocks). This means they cannot work with or make decisions regarding certification for this Plant, but may work with others where no conflict exists.

GFCO also encourages all staff and auditors to report any situation that may impact their ability to treat each Plant impartially.

Plants may refuse the services of an auditor if they feel a conflict of interest exists. This must be done by notifying GFCO and describing the potential conflict that they perceive.

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Complaints and Feedback

Gluten-free certification is a voluntary activity, and GFCO recognizes the extra efforts required by companies that choose to pursue certification. GFCO strives to provide timely, helpful, and accurate customer service to assist companies in achieving and maintaining certification. The following describes the ways in which GFCO-certified companies and applicants can provide feedback, both positive and negative, and how instances of negative feedback will be resolved.

GFCO actively seeks feedback from its clients through annual post-audit surveys and a feedback form available on its website (http://www.gfco.org/contact-us/). In addition, clients regularly provide feedback during phone calls and in emails. While feedback may be positive or negative, this section will focus on feedback provided by clients who are dissatisfied with the service they have received from GFCO and will describe how these concerns are handled.

Notifying GFCO of a Complaint or Concern:
If you have a complaint or concern about your certification, please contact our main office at (253) 218-2956 or email gfco.clientsupport@gluten.org.

Response Timeline:
Many concerns can be handled informally on the day they are received, but some problems require additional research and analyses. For complaints that cannot be handled the day they are received, GFCO strives to provide a solution within 5 business days.

Complaint Resolution:
Most complaints are minor and can be resolved through:

- Explanations of GFCO policies and procedures
- Provision of certificates or other documentation or reports
- Review of the customer's billing statement

Some concerns will require additional investigation and review of information provided by the client and our own internal documentation in order to provide a resolution. These might include concerns about:

- Testing requirements
- Audit frequency
- Ingredient risking

In order to avoid a conflict of interest, personnel that have been previously employed by the Company or one of its direct competitors within the past 2 years may not be involved in these additional investigations and subsequent decisions (though they can resolve minor complaints such as the examples given above). Complaints that identify departures or errors in our management system will also be addressed through GIG's Corrective Action process. The Corrective Action process involves a deeper investigation into the root cause of the error, a proposal of one or more solutions, and a review of the effectiveness of the solution(s). Corrective Actions are reviewed in corrective action meetings, internal audits, and annual Management Reviews. Results of a Corrective Action Investigation may or may not be shared with the company initiating the complaint, depending on the confidentiality of the information in the report.

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Appeals

Companies that have Products certified by GFCO, or companies applying for Product certification through GFCO, can appeal certain decisions that occur during the certification process. The purpose of the appeal is to determine whether GFCO policies were correctly applied in a specific instance. Some of the decisions that can be appealed are:

- Testing requirements assigned to manufacturing and packaging facilities
- The decision to grant or deny certification
- Risk levels for ingredients used in certified Products
- Certification fees

Companies can make an appeal by contacting the customer service representative assigned to their certification, or by contacting the GFCO office at 253-218-2956 or gfco.clientsupport@gluten.org. Any GFCO staff or auditor may also initiate an appeal on behalf of a company.

For all appeal types, any GFCO employee that has been employed by, or done consultancy for, the company involved in the appeal within the previous 2 years may not be involved in the appeal process.

Appeal Process
All appeals are reviewed by a panel of GFCO staff and managers, taking into account GFCO policies. This panel will typically include the GFCO Program Manager, the COO, and other staff familiar with the client, or who filed the appeal on the client's behalf.

The goal of the appeal is to reach a consensus decision. In the event that a consensus cannot be reached, the final decision will be made by the COO.

Impartiality

The GIG Board and Management of GFCO are committed to impartiality in all interactions with our clients and applicants for certification.

Responsibilities:
The COO is responsible for hiring and providing appropriate resources and controls in such a way as to avoid conflicts of interest and to preserve impartiality. GFCO Managers are responsible for training certification personnel and auditors of possible sources of conflict and the requirements for maintaining impartiality.

Identifying Sources of Bias or Conflicts of Interest:
GIG and GFCO recognize that threats to impartiality can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing, and payment of commissions or other inducements for the referral of new clients. These sources of conflict are reviewed at each Management Review meeting, and any known relationships between certified companies, applicants, employees, or auditors are reviewed in order to determine if a conflict exists.

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Measures Taken to Avoid Conflicts of Interest and Safeguard Impartiality:

- Training all personnel and auditors on the potential sources of conflict of interest.
- Specific requirements for hiring personnel that limit those who have been employed by a certified company within the past 2 years.
- Contractual requirements for auditors to eliminate conflicts of interest.
- Training all personnel and auditors on the prohibitions on consulting during the certification and auditing processes.
- Confidentiality agreements with all employees, auditors, and contractors.
- Use of an Impartiality Panel to review sources of potential impartiality.

Impartiality Panel:

The GFCO Impartiality Panel consists of at least three members drawn from key interest groups, including:

- GFCO-certified clients
- Industry representatives
- Members of government regulatory bodies
- Members of NGO or consumer organizations
- Employees of GIG that are not part of GFCO business operations

Although GIG employees may serve on the Impartiality Panel, only one position on the panel may be filled by a GIG employee to prevent predomination of internal interests. The panel must be selected to ensure that it is free from any commercial, financial, or other pressure that might influence its decision.

The Impartiality Panel is authorized to review the operations and procedures of GIG and GFCO and to review de-identified client documentation as it pertains to specific cases for review. Impartiality Panel members must respect the confidentiality requirements of GFCO and its clients and will complete non-disclosure/confidentiality agreements with GFCO before serving on the Panel.

The initial members of the Panel were appointed by the GIG CEO for a term of 1 year, but continuing annual appointments are made by the Panel itself. The requirements for appointment are that the person be open-minded, ethical, and diplomatic (as judged by the Panel), and have knowledge of the certification process (by being employed or certified by GIG/GFCO) or of the gluten-free industry (as evidenced by employment history). Panel members may be re-appointed to additional one-year terms, but may not serve for more than 5 consecutive years or 8 years in total. GFCO retains the authority to appoint and withdraw members of this Panel as needed.

The Impartiality Panel meets once per year either in-person, via teleconference, or by video conference. The GFCO Regulatory Manager or GFCO Program Manager moderates the meeting to provide clarification on questions and procedural guidance. Minutes will be recorded by an additional, non-participating, GIG employee or by the use of a recording device with the consent of all attendees.

The agenda for the Panel meetings will consist of:

- Review of the role, purpose, and responsibilities of the Panel
    - Input on policies and principles relating to impartiality of certification
    - Feedback on observed tendencies of GFCO to allow commercial or other considerations to prevent consistent, impartial provision of certification activities

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    - Review of matters affecting impartiality and confidence in certification, including openness.
- Completion of non-disclosure/ confidentiality agreements for new members
- Review of CAPAs from the previous meeting
- Review of the impartiality of the audit process
- Review of the impartiality of the certification process, including certification decisions
- Review if any possible sources of bias uncovered during the previous Management Review meeting
- Review of the impartiality of any decisions to withdraw certification during the previous year
- Appointment of the next Panel

Following the meeting, a report of the meeting minutes and initiate any action items that resulted from the discussion will be prepared. GFCO Management is committed to acting on input from the Impartiality Panel through its Corrective and Preventive Action Procedures, provided that input does not directly conflict with GFCO procedures and standards. If recommendations from the Panel are not implemented for this reason, it will be documented as such on the applicable Corrective/Preventive Action report. If GFCO elects not to act on input from this Panel, the Panel has the right to take independent action, as long as they adhere to the confidentiality requirements of GFCO and its clients.

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Additional Information

Ingredient Sampling Plans

There are two ingredient sampling/testing plans suggested here, one for ingredients with a small particle size and relatively homogeneous composition (while recognizing the heterogeneity that occurs at a microscopic level), and the other for macroscopically heterogeneous ingredients.

Examples of each ingredient type are provided below. When sampling Risk Level 3 items, chose the container to be sampled randomly – for example, don't always sample the first or last tote or pallet unloaded. Use a random number generator if needed to ensure that there is not a pattern to the selection of the container for sampling. Testing must be done by lot whenever lot information is available or by shipment/harvest.

Sampling for Ingredients with Small Particle Size or Relative Homogeneity

Examples include flours, ground materials, powders, creams, pastes, syrups, and well-mixed liquids.

Sampling Plan: For each container being tested, use an appropriate sampling tool that will allow the collection of material from the top to the bottom of the container, such as a trier, slot sampler, lance, or extended syringe. Take one representative sample of the ingredient per container using this sampling tool. Take 100g of this sample, using an appropriate splitting method, and grind it to the consistency of a flour. Test a portion for gluten using a GFCO-approved method, or the services of an ISO 17025 accredited laboratory. Keep the remainder of the sample for any follow-up testing. Any confirmed positive result from a rapid (lateral flow) test method must be confirmed by a quantitative assay performed by an ISO 17025 accredited testing laboratory. If the gluten value plus the laboratory's measurement uncertainty estimate is greater than the Applicable Gluten-Free Threshold, the entire ingredient lot/shipment cannot be used in a certified Product.

Sampling for Ingredients with Large Particle Size or Relative Heterogeneity

Examples include grains, seeds, nuts, beans, and legumes.

Sampling Plan: For whole intact grains, seeds, beans, pulses, legumes, or nuts, you can inspect them on receipt by using visual examination, or through antibody-based testing. For other large particle ingredients (for example, rolled or flaked grains), you will use antibody-based testing.

For visual examination, use the sampling plan described on page 26 for Finished Products.

To perform antibody-based testing for large-particle-size samples, for each container being tested, use an appropriate sampling tool (trier, slot sampler, or lance). For small containers (50 lb bags or smaller), take one sample from throughout the bag; for large containers such as totes, take six representative samples per container – one near each corner of the container and two near the center. Reduce each sample to 500g using a Boerner divider or by coning and quartering, and grind them individually to the consistency of a flour. Individually test each sample (do not composite) for gluten using a GFCO-approved method, or the services of an ISO 17025 accredited laboratory. Keep the remainder of each sample separate, and store them in the event that further testing is required. In the event of a confirmed positive (greater than the Applicable Gluten Free Threshold) result from a rapid (lateral flow) test method, the remaining portion of each sample must be tested individually using a quantitative method at an ISO 17025 accredited testing laboratory. If the gluten value of any sample plus the laboratory's measurement uncertainty

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estimate is greater than the Applicable Gluten Free Threshold, the entire ingredient lot cannot be used in a certified Product.

Training and Competency Evaluation for Testing Staff

Requirement 71 of the GFCO Certification Standard states that “All Plants and Brand Owners performing testing in their own facility must have documentation of the training of the employees performing the tests, including annual competency testing”. This section will give you some ideas for meeting this requirement.

The first thing that requirement 71 asks for is training. Any employee who will test ingredients or finished products for gluten, or who will do swab testing, must be trained on the test method. Start by choosing a test method from the GFCO Approved Kit list. If your plant is new to testing, ask the kit manufacturer if they can provide you with
a video or other training materials, and keep a record of the staff who take this training. This is also a good idea if your plant has been testing for a while but does not have records that show that the staff has been trained. Once you have trained one or more of your staff members, they can provide training to new employees.

Keep records of all training. Write down the training date, the names of the staff members that were trained, and how the training was done (e.g., watched a video from a kit manufacturer, or demonstration from current testing staff). Your training records can also include results from any quizzes, or observation notes from the staff member giving the training.

Once your staff have training records on file, you will want them to show that they are competent at testing. One quick way to do this is to have a trained supervisor pick 2 or more food samples, some with gluten and some without. The supervisor will test the gluten content of each sample using your in-house test kit, then package these samples to conceal their identity, keeping a private record of each sample’s gluten result. The “blinded” samples are then given to the testing staff as unknowns, to be tested and recorded like all other samples. For swabbing, the supervisor can intentionally contaminate a surface with gluten-containing or gluten-free materials. Competence can then be shown by comparing the test results obtained by each staff member to the known gluten content of the samples/surfaces, as well as by confirming that each staff member is recording the test results correctly.

Competency can also be assessed by splitting 2 or more samples and having one set tested by a staff member and the other set tested by an independent ISO 17025 accredited laboratory, or by assigning a staff member to participate in the plant’s proficiency testing round. In every case, the staff member’s testing results and quality of test records/reports should be evaluated. The results of all competency evaluations should be recorded, and any errors should be followed by re-training or other corrective action.

Competency evaluation should be done each year for all staff that perform gluten testing. Keep in mind that **competency evaluation and proficiency testing are two separate things**. Competency evaluation is designed to show that your staff are performing testing according to your internal procedures, but proficiency testing is meant to show that your testing procedures give results that are in line with all other test kit users.

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The GFCO Certification Standard

The GFCO Standard is to be used by GFCO-approved auditing and product certification bodies when determining the conformity of a product and production process to GFCO requirements. This standard covers the organizational requirements of the client, assessment of the gluten program of the client, certification testing, and surveillance by testing of product samples taken from the factory and/or the open market. This standard also addresses conditions for use of the GFCO certification mark and conditions for granting a GFCO Product certificate. The GFCO Certification Standard follows a Scheme Type 5 product certification as described in ISO/IEC 17067:2013.

This standard is intended for use only with products produced in batches or lots, and due to the sampling methods used in the system cannot be used to certify groups of individually prepared items.

References:
The following referenced documents were consulted or cited in the development of this standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories.
- US-FDA, January 2009. Guidance for Industry – Voluntary Third-Party Certification Programs for Foods and Feeds.
- ISO/IEC 17007:2009. Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment.
- CAC/GL 20-2007. Principles for food import and export inspection and certification.
- CAC/GL 26-1997. Guidelines for the design, operation, assessment, and accreditation of food import and export inspection and certification systems.
- ISO/IEC 17030:2021. Conformity assessment – General requirements for third-party marks of conformity.
- ISO/IEC 17026:2015. Conformity assessment – Example of a certification scheme for tangible products.
- ISO/IEC 17067:2013. Conformity assessment – Fundamentals of product certification.
- ISO/IEC 17065:2012. Conformity assessment – Requirements for bodies certifying products, processes, and services.
- GFSI Benchmarking Requirements, version 2020

Beneath each GFCO Standard requirement, a rationale or interpretation has been provided, as well as examples of the types of evidence an auditor might look for in order to determine compliance. These evidence examples are not comprehensive and each manufacturing facility must meet each requirement in the manner that best meets their operations. The text of each Standard requirement is provided in plain text, with additional explanatory material given in italics.

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GFCO STANDARD

Organizational Requirements

Brand Owner:

1. **The Brand Owner or organization of which it is a part must be an entity that can be held legally responsible.**
    - *Rationale: GFCO is executing a contract with the applicant, so evidence of the applicant's legal status is required.*
    - *Example Evidence: Incorporation documents, a current business license, evidence of a current business registry with the state, or any other proof of the business's legal status. If the Brand Owner and the manufacturing plant(s) are separate entities, this evidence will not be reviewed during the facility audit but should be available upon request.*
2. **The Brand Owner organization must develop and support a policy that states the organization's intent to supply safe gluten-free products that meet all GFCO requirements. The policy must outline the organization's commitment to continuous improvement, including a commitment to produce safe, legal, and GFCO-compliant gluten-free products, and be signed by a senior executive. The policy must be communicated to all staff and contractors within the organization, and be publicly available**.
    - *Rationale: Certification is a process that affects all levels of a company's policies and procedures. A written statement from company management indicating their intention to comply with the GFCO Standard requirements is an indication of management's awareness of and commitment to the certification process.*
    - *Example Evidence: A written statement in any document that is approved/signed by company management, such as in a Quality Manual or Operations Manual that is available to all staff. If the Brand Owner and the manufacturing plant(s) are separate entities, this evidence will not be reviewed during the facility audit but should be available upon request.*
3. **The Brand Owner must declare the countries where the certified products will be Publicly Sold, and maintain documentation of the gluten-free labeling regulations in those countries. The Brand Owner must meet all applicable local, regional, national, and international requirements for packaging, representation, and sales of the product(s).**
    - *Rationale: Gluten-free labeling regulations differ from country to country, and GFCO certification does not supersede national, international, or local law. Companies selling certified product must have evidence of their awareness of gluten-free labeling regulations in each country where certified product is sold.*
    - *Example Evidence: Any physical or electronic documentation of countries of sale, and the gluten-free regulations in those countries, that is approved by company management. If the Brand Owner and the manufacturing Plant(s) are separate entities, this evidence must be shared with the Plant(s).*
4. **The Brand Owner must define and specify the activities of all key personnel involved in all steps in the development, sales, marketing, and support of the certified product, including the organization and management structure of the**

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company, its connection to any manufacturers/co-producers/co-packers, and its place in any larger organization.

- *Rationale: An organizational chart allows GFCO to see the reporting structure of those personnel and companies involved in the production of the certified product, and to observe any potential conflicts of interest*
- *Example Evidence: An organizational chart or charts, or some other description of the organization and management structure of the company. If the Brand Owner and the manufacturing plant(s) are separate entities, this evidence will not be reviewed during the facility audit but should be available upon request.*

5. **All personnel involved in development, sales, marketing, and customer service related to the certified product(s) must have annual training on gluten and its health effects. Records must be maintained that verify the effectiveness of this training.**
    - *Rationale: Awareness of gluten and its health effects is essential in every position that interacts with the public. Consumers purchasing certified products should be able to obtain knowledgeable answers about those products from the Brand Owner. This training requirement only applies to the direct employees of the Brand Owner's company, not to outside marketers or distributors*
    - *Example Evidence: Training materials and training records for all personnel that interact with the public. The training should include an evaluation component, such as a quiz, to measure the effectiveness of training. Training should at a minimum address the sources of gluten (wheat, rye, barley, and related grains), as well as the fact that celiac disease is a serious health concern. If the Brand Owner and the manufacturing plant(s) are separate entities, this evidence will not be reviewed during the facility audit but should be available upon request.*
6. **The Brand Owner must identify a key position to act as primary contact with GFCO and the Plants that manufacture the certified product(s). A secondary contact must be appointed to act on this person's behalf in the event of their absence.**
    - *Rationale: GFCO requires a primary and backup contact for all companies applying for certification. These employees will also serve as the contacts between the Brand Owner and the manufacturing plant(s) if they are separate entities. Having a backup contact helps to ensure the continuity of the certification program*
    - *Example Evidence: Personnel named to these positions in job descriptions or organizational charts. If the Brand Owner and the manufacturing plant(s) are separate entities, this evidence will not be reviewed during the facility audit but should be available upon request.*
7. **The Brand Owner must maintain complete documentation of their certified Products, and any updates to the certified Product list must be submitted to GFCO immediately in order to maintain certification.**
    - *Rationale: The GFCO logo may only be applied to Products that appear on the company's certificate. It is imperative that GFCO review and approve any new Products, and issue a certificate with the new Products, prior to the appearance of the GFCO logo on any packaging. The Brand Owner must keep accurate documentation of their certified Products, in either physical or electronic format, to provide to the manufacturing Plant(s), in order to avoid mislabeling.*

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- *Example Evidence: A Product list, either physical or electronic, maintained by the Brand Owner that matches the list on file with GFCO, as well as the certificate. If the Brand Owner and the manufacturing Plant(s) are separate entities, the Brand Owner must share a copy of this list with the Plant.*

8. **If the Brand Owner is responsible for the product formulations, then the Brand Owner must maintain complete documentation of approved ingredients and suppliers, and any changes to the ingredients, ingredient components or ingredient suppliers must be submitted immediately to GFCO in order to maintain certification. The Brand Owner and Plant must arrange which party will be responsible for submitting a complete list of products and their ingredients to the certification body as part of the application for certification.**
    - *Rationale: GFCO certification is dependent on the evaluation and risking of all Ingredients used in certified Products. Ingredients that have not been reviewed, risked, and approved by GFCO may not be used in certified Products. If the Brand Owner is not involved in the Product formulation, this requirement is not applicable.*
    - *Example Evidence: An ingredient list, in physical or electronic format, maintained by the Brand Owner that matches the list on file with GFCO. If the Brand Owner and the manufacturing Plant(s) are separate entities, the Brand Owner must share a copy of this list with the Plant.*
9. **The Brand Owner must provide GFCO with a list of commercial retailers of their certified products upon request, if applicable.**
    - *Rationale: GFCO performs surveillance testing of retail-certified Products, and must be able to procure retail samples for this testing. The Brand Owner must be able to provide the names or locations of retailers or online sources where their certified Products can be found. This requirement does not apply to manufacturers of wholesale Products.*
    - *Example Evidence: A list of some or all of the retail locations/websites where the Brand Owner's retail products can be purchased. This evidence will not be reviewed during the facility audit but should be available upon request.*

Plant:

10. **The Plant or organization of which it is a part must be an entity that can be held legally responsible.**
    - *Rationale: GFCO may execute a contract with the plant, and the plant must be a legal entity that is responsible for the safety of its products, so evidence of the facility's legal status is required.*
    - *Example Evidence: Incorporation documents, a current business license, evidence of a current business registry with the state, or any other proof of the business's legal status.*
11. **The Plant must develop and support a policy that states their intent to supply safe gluten-free products that meet all GFCO requirements. The policy must outline the Plant's commitment to continuous improvement, include a commitment to produce safe, legal, and GFCO-compliant gluten-free products, and be signed by a senior**

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executive. The policy must be communicated to all staff and contractors within the organization, and be publicly available.

- *Rationale: Certification is a process that affects all levels of a company's policies and procedures. A written statement from company management indicating their intention to comply with the GFCO Standard requirements is an indication of management's awareness of and commitment to the certification process.*
- *Example Evidence: A written statement in any document (physical or electronic) that is approved/signed by company management, such as in a Quality Manual or Operations Manual.*

12. **If the Plant is responsible for packaging design or product distribution, the Plant must maintain documentation of the countries where the certified products will be Publicly Sold, and maintain documentation of the gluten-free labeling regulations in those countries. If the Brand Owner(s) operating in the Plant is responsible for packaging design or product distribution, the Plant must request and keep a current copy of the Brand Owner's documentation of countries where the certified products will be Publicly Sold, and of the gluten-free labeling regulations in those countries. In all cases, the Plant must meet all applicable local, regional, and/or national requirements for production and packaging of the product(s).**
    - *Rationale: GFCO can only certify Products that are produced according to all local, regional, and national regulations.*
    - *Example Evidence: Food manufacturers must have a permit to manufacture and sell food, granted by their state or equivalent level of government. Other businesses must be able to provide all required local, state, or national permits to manufacture or sell, as required by their industry. All must have documentation (physical or electronic) of the countries where their certified products are sold, including the gluten-free labeling regulations in those countries.*
13. **The Plant must have an appropriate collection of written procedures in place that specifically address gluten control, which will be referred to as the Plant's "Gluten Program." This Gluten Program does not need to be a unique, stand-alone set of documents, although it may be. The Gluten Program may be comprised of policies and procedures located in other management system documents, as long as those documents clearly refer to, and correctly define gluten. The Gluten Program must include a current copy of the GFCO Standard.**
    - *Rationale: An essential part of managing gluten risks is a clear set of policies and procedures for gluten management. Written policies and procedures are also necessary for the continuity of the plant's gluten control system in the event of staffing changes.*
    - *Example Evidence: A collection of policies and procedures that cover the requirements of this Standard, and any other policies and procedures deemed essential for gluten control by the plant. The gluten program does not need to be a separate set of policies and procedures – the gluten management processes can be included within the plant's other documentation. However, the policies and procedures must name and specifically address gluten and its risks.*

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14. **The Gluten Program must cover work carried out in the Plant's permanent facilities, at co-producers or co-packers, or in any other associated permanent, temporary or mobile facilities involved in the production of certified Product(s).**
    - *Rationale: GFCO needs to audit all of the major steps in the manufacture of certified Products. If a company uses several facilities to complete all of the manufacturing steps for a certified Product, each of those facilities must be covered by a set of written policies and procedures for gluten control, either separately or collectively.*
    - *Example Evidence: A collection of written policies and procedures that cover the requirements of this Standard at each facility involved in manufacturing the certified Product(s).*
15. **The Plant must carry out their production activities in such a way as to meet the requirements of their Gluten Program and of this Standard for all certified Products. This includes an annual Plant Registration with the GFCO program, at which time the Plant will confirm its awareness of all GFCO requirements.**
    - *Rationale: The GFCO Standard requirements cover the major aspects of gluten control that are applicable across most industries. Individual companies should also assess gluten risks that are specific to their industry and their facilities, and create internal policies and procedures to address those risks.*
    - *Example Evidence: The auditor will look for evidence that the plant is adhering to the GFCO Standard as well as to any additional gluten control measures that the plant has determined are required for safe gluten-free production, and will also confirm that the plant's registration is current.*
16. **The Plant must define and specify the activities of its key personnel involved in the creation of the certified product(s), and define the organization and management structure of the company, including its connection to any co-producers/co-packers, its place in any larger organization, and the relationship between quality management and production operations.**
    - *Rationale: An organizational chart allows GFCO to see the reporting structure of those personnel and companies involved in the production of the certified product, and to observe any potential conflicts of interest.*
    - *Example Evidence: An organizational chart or charts, or some other description of the organization and management structure of the company.*
17. **The Plant must have personnel with the authority and resources to implement the Gluten Program, including the program's maintenance and improvement.**
    - *Rationale: The Gluten Program must be administered by a person or persons within the organization who have the authority to make or suggest changes and improvements in operations.*
    - *Example Evidence: The appointment of someone in the organization, who holds a position of responsibility and authority, to implement, maintain, and improve the gluten program. This may be indicated in job descriptions, job titles, or other organization documents, and by the employee's understanding of their job duties.*
18. **The Plant must identify a key position to act as primary contact with GFCO for all matters related to certification. An alternate contact must be appointed to act on this person's behalf in the event of their absence.**

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- *Rationale: GFCO must have a designated contact person in all facilities that manufacture certified Product. Having a backup contact helps to ensure the continuity of the Gluten Program.*
- *Example Evidence: Personnel named to these positions in job descriptions, organizational charts, or other plant documentation, and employee understanding of these job duties.*

19. **The Plant must have personnel with the authority and training to identify departures from the Gluten Program and to initiate action to prevent, correct, or minimize such departures.**
    - *Rationale: Someone within the organization must be assigned to monitor the Gluten Program and initiate preventive or corrective actions.*
    - *Example Evidence: Personnel assigned these duties in job descriptions, organizational charts, or other plant documentation, evidence of employee understanding of these responsibilities.*
20. **The Plant must provide adequate supervision of production staff by persons familiar with the Gluten Program.**
    - *Rationale: The supervisor or manager on each production shift where a certified Product is manufactured must be trained on the plant's Gluten Program.*
    - *Example Evidence: Training materials, training records, job descriptions, shift assignments, or other means for indicating that the manager or supervisor for each shift where a certified Product has been produced has been trained on the Gluten Program. Evidence that production staff know who is in charge of the Gluten Program on their shift.*
21. **The Gluten Program requirements must be communicated to, understood by, available to, and implemented by the applicable personnel. All personnel operating under the Gluten Program must have annual training on their roles and responsibilities and in its maintenance. Training on the Gluten Program must also include information on the potential sources of gluten (wheat, rye, barley, and, where applicable, oats), training on the potential health effects of gluten for persons with celiac disease and non-celiac gluten sensitivity, and training on how staff can report suspected gluten contamination/cross-contact. Training must be provided to all applicable personnel involved in administration and manufacturing as well as those in marketing and those that interact with consumers.**
    - *Rationale: All employees involved with certified Products must be trained on the components of the Gluten Program that are relevant to their job duties, including management, supervisors, production staff, marketers, purchasing, R&D, product development, customer service, etc. The written policies and procedures that these employees are trained on should be available to them at all times.*
    - *Example Evidence: Training materials on the Plant's Gluten Program, gluten sources, and gluten risks. Training for all staff must address the sources of gluten (wheat, rye, barley, and related grains), as well as the fact that celiac disease is a serious health concern. Evidence of the availability of relevant policies, procedures, or work instructions.*
22. **The effectiveness of the training provided under requirement 21 must be evaluated, and records must be maintained that attest to the effectiveness of this training.**

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- *Rationale: All personnel manufacturing under the Gluten Program, and those communicating outside of the company in regards to the certified Products, must demonstrate awareness, at a minimum, of the sources and risks of gluten. Those in specific roles must demonstrate additional understanding of their duties in the production of gluten-free Products.*
- *Example Evidence: Training records for all applicable personnel. Evidence that employees know the sources of gluten and the risks of gluten. The training records must include an evaluation component, such as a quiz or documentation observation by management, to measure the effectiveness of training.*

23. **Plant management must provide evidence of commitment to the implementation and continual improvement of the Gluten Program through, at a minimum, annual reviews of the program and its effectiveness.**
    - *Rationale: The Gluten Program must be regularly reviewed at least annually, and improved as needed.*
    - *Example Evidence: Meeting notes where management has reviewed the gluten program, records of staff meetings discussing the program and its implementation.*
24. **The Plant must have procedure(s) in place to guarantee the continuity of the Gluten Program regardless of changes in staffing or management.**
    - *Rationale: The Gluten Program must operate consistently even when there are personnel changes in the plant. Continuity can be aided by the appointment of back-ups to personnel who maintain the program, employee training on written policies and procedures, and management commitment to the program.*
    - *Example Evidence: Job descriptions assigning primary and secondary personnel to maintain the Gluten Program; evidence of employee training on and understanding of appropriate policies and procedures; evidence of management commitment, e.g. assigning sufficient personnel and resources to the program.*
25. **Appropriate control of the Gluten Program documentation must be shown, including a system for periodic review and revision as necessary, evidence of document approval, and the availability of only approved, current versions of all documents.**
    - *Rationale: It is essential that all policies and procedures in the Gluten Program be reviewed and approved by management before use, and that employees only have access to the current versions of all documents.*
    - *Example Evidence: Documents that have unique names and revision numbers, an indication that documents have been reviewed and approved before release, a lack of conflicting document versions available to staff, evidence that staff are informed of document updates.*

Production and Product Requirements

Production and product requirements are composed of two sections: the Plant's Gluten Program and its implementation, and product and ingredient testing.

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The Plant's Gluten Program must address the following processes:

Purchasing and Receipt of Raw Materials:

26. **The Gluten Program must contain a procedure for the selection and approval of raw materials and vendors for those materials. This procedure must specify the documentation that the client will accept from each vendor, such as vendor statements, testing data, or 3rd party certification, to ensure that all raw materials meet the GFCO definition of Gluten-Free. This process may be handled by either the Brand Owner or the Plant, depending on which party is sourcing raw materials. If the Brand Owner is supplying raw materials to the Plant, the Plant must receive and maintain copies of all vendor documents obtained by the Brand Owner that serve as records of the gluten-free status of those materials.**
    - *Rationale: A vendor and raw material approval process is an essential part of ensuring the safety of gluten-free finished Products. It can also reduce the likelihood of product recalls and withdrawals.*
    - *Example Evidence: a written procedure for vendor and raw material approval. Statements or testing data as required by the procedure. Evidence that purchasing staff are aware of the procedure. Vendor documents.*
27. **The Plant must maintain a list or documentation of approved vendors and raw materials.**
    - *Rationale: Once vendors and raw materials have been vetted, the plant should ensure that only those vendors and raw materials are used to manufacture certified Product.*
    - *Example Evidence: A list or other documentation of approved vendors, either physical or electronic, including the raw materials that can be purchased from each. Evidence that purchasing staff are aware of and using the list. Purchasing records that only show purchases of approved raw materials from approved vendors.*
28. **The Gluten Program must contain a procedure for the creation, use, review, and maintenance of purchasing documents for all materials used in the production of gluten-free products.**
    - *Rationale: Purchasing documents are essential for traceability*
    - *Example Evidence: Written procedures for creating, using, reviewing, and maintaining purchasing documents. The presence of purchasing documents for gluten-free materials, that have been kept for a time period determined by the plant, but at least as long as the products might be available for sale. Evidence that staff understand how to use and prepare the purchasing documents.*
29. **Purchasing documents must use specific descriptions for the materials being requisitioned. In particular, if a supplier offers both gluten-free and non-gluten-free versions of the same raw material, purchasing documents must clearly request the gluten-free version.**
    - *Rationale: Many suppliers sell both gluten-free and non-gluten-free versions of their raw materials. Purchasing documents should clearly indicate if a gluten-free or certified gluten-free item is being requested, and include any requests for certificates of analysis or gluten-free certificates.*

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- *Example Evidence: Purchasing documents for gluten-free raw materials that clearly indicate a specific part number, product name, or other means to ensure that gluten-free material is purchased. If the facility requires COAs or certificates with raw materials, evidence that these are requested on purchasing documents*

30. **The Gluten Program must include procedures for receiving raw materials including inspecting incoming trucks and shipments for cleanliness and potential gluten cross-contact, and verification that the correct materials are received. Records of these checks must be maintained.**
    - *Rationale: The plant must ensure that they are receiving the correct raw materials for gluten-free production and that the transports delivering these raw materials are not a source of gluten contamination.*
    - *Example Evidence: Written procedures for receiving that include checking the shipment for accuracy and checking the transports for gluten contamination. Documentation that the shipment checks and transport checks have occurred. Evidence that receiving staff understand the receiving procedures.*
31. **The Gluten Program must contain instructions for labeling incoming materials in such a way that they are uniquely identified and cannot be confused with other materials or material lots.**
    - *Rationale: The plant must ensure that raw materials received for gluten-free production cannot be confused with raw materials that may contain gluten. This requirement is not audited in facilities that are dedicated to gluten-free production.*
    - *Example Evidence: Written procedures for labeling incoming raw materials to either highlight their gluten-free status or to highlight the presence of wheat/gluten. Observation of proper labeling.*
32. **The Gluten Program must contain procedures for maintaining separation between gluten-containing and gluten-free materials during receipt, storage, and usage, as applicable. At a minimum, gluten-free materials must be stored above gluten-containing materials to prevent gluten cross-contact in the event of spillage.**
    - *Rationale: Gluten-free and gluten-containing raw materials must be segregated in receiving, in storage, and during use in order to prevent cross-contamination. This requirement is not audited in facilities that are dedicated to gluten-free production.*
    - *Example Evidence: Written procedures for segregating raw materials at receiving, in storage and during use. Observation of proper segregation during receiving, storage, and production, for example: gluten-containing and gluten-free materials stored in separate rooms or on separate shelving, or at a minimum, gluten-free materials stored above gluten-containing materials; observation that gluten-free work in progress is covered or kept separate from gluten-containing WIP. Evidence that staff understand the segregation requirements*
33. **The Plant must maintain up-to-date documentation of all ingredients received in the plant that are used in certified gluten-free production, including the name of each supplier, unique identifiers for each ingredient that agree with the ingredients' labeling, and the Ingredient Risk Factor for each Ingredient as assigned by GFCO. The Plant is responsible for requesting this information from the Brand Owner if needed.**
    - *Rationale: The plant must ensure that the raw materials they receive are the same ones that they have vetted and approved and that each raw material has a unique*

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identifier for purposes of traceability. It is essential that each Plant know the risk scores for the ingredients used in certified Products.

- *Example Evidence: An ingredient list maintained by the plant that matches the list on file with GFCO, and that shows the risk score for each ingredient. Observation of unique labeling on each raw material used in certified gluten-free production. Evidence that employees can properly identify materials used in certified gluten-free production.*

34. **If the Plant is responsible for the formulation of the certified product(s), any updates or alterations to the ingredient list or supplier list must be submitted immediately to the certification body in order to maintain certification. The Brand Owner and Plant must arrange which party will be responsible for submitting a complete list of products and their ingredients to the certification body as part of the application for certification.**
    - *Rationale: GFCO certification is dependent on the evaluation and risking of all Ingredients used in certified Products. Ingredients that have not been reviewed, risked, and approved by GFCO may not be used in certified Products.*
    - *Example Evidence: An ingredient list maintained by the plant that matches the list on file with GFCO*

Facilities and Equipment:

35. **The Gluten Program must include a requirement for the display or availability of applicable instructions at all manufacturing locations describing how best to avoid gluten cross-contact. For example, instructions for equipment cleaning and surface testing must be made available near any equipment that is used for both gluten and certified gluten-free Product manufacturing. If instructions cannot be posted in the plant, those instructions must be available near the production floor entrance.**
    - *Rationale: Plants must make their best practices for gluten-free production available to employees at all times – keeping them in a binder in someone's office doesn't allow staff to review them as needed.*
    - *Example Evidence: Observation of relevant sections of the written Gluten Program in areas where staff can access them – as posted instructions in work areas, or in break or dressing areas where they can be readily seen by staff.*
36. **The Gluten Program must include schedules for facility and equipment cleaning and maintenance.**
    - *Rationale: Regular cleaning schedules are essential for maintaining a gluten-free production environment.*
    - *Example Evidence: Written cleaning schedules. Documentation that scheduled cleaning has occurred. Evidence that staff understand cleaning schedules.*
37. **The Gluten Program must include instructions for effective cleaning and maintenance of facilities, equipment, and work tools. These instructions must be displayed or made easily available to employees at all times.**
    - *Rationale: Cleaning protocols should be validated or verified to make sure they are effective. The written instructions for the validated/verified protocol(s)must be available to the cleaning staff.*
    - *Example Evidence: Written cleaning protocols with evidence that their effectiveness has been demonstrated. The observation is that these protocols are*

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available to staff. Evidence that staff understand these protocols and are performing them correctly.

38. **The Gluten Program must include specific instructions for cleaning between the production of gluten-containing and certified gluten-free Product, if applicable, and the methods for verifying the cleaning processes for facilities, equipment, and work tools during production and packaging.**
    - *Rationale: Changeover between gluten-containing and gluten-free production runs is a high-risk process and requires specific cleaning protocols – these may be the same as the plant's regular cleaning protocols, but they must be validated for use between gluten-containing and gluten-free runs, and they must cover the changeovers that occur in production and packaging. In addition, the cleaning effectiveness at these changeovers must be regularly verified or re-validated. This requirement is not audited in facilities that are dedicated to gluten-free production.*
    - *Example Evidence: Written cleaning protocols that are specific to, or have been specifically validated for, changeovers between gluten-containing and gluten-free production. Evidence that these procedures are regularly verified or re-validated (swab testing following each cleaning, or re-validation of the cleaning process at least every 6 months). Documentation that these cleaning procedures are being performed in all areas of production and packaging, such as a check-off sheet. Evidence that staff understand the cleaning protocols and verification/re-validation process.*

Production Processes:

39. **The Gluten Program must include a written analysis of the production process, including identification of all points at which gluten cross-contact or mislabeling might occur. Any changes in facilities, equipment, formulations, suppliers or any other aspect of production must be reviewed for their potential risk to the gluten-free status of certified Products. If a potential risk is identified, plant management must analyze this risk and implement methods to mitigate the risk. Records of this analysis and mitigation plan must be maintained.**
    - *Rationale: The production facility should have a HACCP plan or other analysis of the production process that identifies the risk points for gluten contamination or product misidentification in their processes. This can be done through a plant diagram or written description of the process and can be part of the plant's overall risk assessment. Dedicated gluten-free facilities should at a minimum recognize the risks from incoming raw materials, and from materials that might be introduced into the plant by employees. The risks identified should then be addressed by the plant's Gluten Program.*
    - *Example Evidence: A written description of the production process that identifies gluten risk points, and evidence that each risk identified is addressed by the plant's policies and procedures. Observation of identified and unidentified risk points.*
40. **The Gluten Program must include a requirement that each product be prepared from a detailed recipe/batch sheet/order, including a specific product number or unique name for each ingredient/raw material/formulation/process.**

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- *Rationale: Accurate, detailed batch records are necessary for traceability of both Products and raw materials.*
- *Example Evidence: Observation of batch sheets for each lot of certified Product that clearly identify the raw materials used in production as well as the Product batch.*

41. **The Plant must possess up-to-date documentation of certified Products manufactured in the plant, including unique identifiers for each Product that agree with the Products' labeling. The Plant is responsible for requesting this information from the Brand Owner(s) if needed.**
    - *Rationale: The plant must know which Products are certified, to avoid mislabeling. The Product names on this documentation must match the Product names on the certificate and the Product packaging.*
    - *Example Evidence: A Product list maintained by the plant that matches the list on file with GFCO, as well as the certificate and any observed Product packaging.*
42. **If the Plant is responsible for maintaining the list of certified Products, any updates to the Product list must be submitted immediately to the certification body in order to maintain certification.**
    - *Rationale: The GFCO logo may only be applied to Products that appear on the company's certificate. It is imperative that GFCO review and approve any new Products, and issue a certificate with the new Products, prior to the appearance of the GFCO logo on any packaging. The plant must keep an accurate list of certified Products.*
    - *Example Evidence: A Product list maintained by the plant that matches the list on file with GFCO. Evidence that updates have been submitted to GFCO if the Plant is responsible for the Product list*
43. **The Gluten Program must include a procedure for ensuring that the correct recipe/formulation is used for each Product lot, including documentation that the recipe/formulation was verified.**
    - *Rationale: The plant must verify that they are making the intended product during each production run and that the correct formulation is used for that product. The product and formulation should be reviewed before each production run.*
    - *Example Evidence: Documentation that the product being made as well as its formulation is reviewed and approved before each production run, such as a sign-off on the batch record. Evidence that staff know who must approve each production run.*
44. **The Gluten Program must include a requirement that records be kept for each lot of Product; these records must include the Product lot number, date of production, size of a production lot, the identity of all equipment, machinery, and packaging used in production as well as the product identification, volume and lot number of each raw material used. This batch record must be signed or verified by the employee preparing the lot, or by the production supervisor if multiple employees are involved in recipe preparation. These batch records must be maintained and available for a suitable period as determined by the client, but at least as long as the Product might be used by the public.**

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- *Rationale: Production batch records must contain sufficient information to allow traceability and investigation of contamination incidents, and must be kept for as long as the Product might be available for sale. Completed batch records should be reviewed for accuracy and completeness following each production run.*
- *Example Evidence: Batch records that contain all of the listed information, with evidence that they have been reviewed and accepted as accurate and complete.*

45. **The Gluten Program must include a procedure for ensuring that the correct raw ingredients and packaging were used in the preparation of each lot and that a review of this information is documented prior to the release of the lot.**
    - *Rationale: The use of incorrect raw materials and mispackaging/mislabeling are two major risks in gluten-free production. Review of raw materials and packaging/labeling are essential to safe gluten-free production.*
    - *Example Evidence: Indication that raw materials were reviewed as part of the batch record review process. Indication that packaging and labels are reviewed, either within the batch record review or as a separate review step. Evidence that staff are aware that packaging/labels must be reviewed for each packaging run.*
46. **The Gluten Program must include a procedure for making recipe/formulation changes, including assigning authority for making and approving changes, as well as assigning responsibility for distributing the new recipe to employees and assuring its availability at all required locations.**
    - *Rationale: Any changes to the formulation of a gluten-free Product must be made by someone who is authorized to make those changes. Any formulation changes should be documented, clearly communicated, and available to employees.*
    - *Example Evidence: Assignment of an authorized person or persons to make formulation changes, as seen in job descriptions or other documentation of job duties. Observation that formulations have been reviewed and approved prior to use, such as a signature from the authorized employee. Evidence that staff know where to find current formulations. Evidence that there are not multiple versions of formulations available to production staff.*
47. **The Gluten Program must include a requirement that all employees, maintenance workers, contractors, and visitors observe hygiene requirements including hand washing, clothing requirements, and other manufacturing procedures that will eliminate cross-contact.**
    - *Rationale: Gluten contamination can be introduced by persons entering the plant, so everyone who has access to the plant should observe hygiene requirements.*
    - *Example Evidence: Written hygiene requirements that apply to everyone who might enter the plant. Observation that auditor was asked to observe these requirements. Observation that staff are observing the requirements when entering the facility.*
48. **In Plants that process gluten-containing and gluten-free products, the Gluten Program must include procedures for sequencing production activities to eliminate carryover or cross-contact.**
    - *Rationale: Changeover between gluten-containing and gluten-free products is a high-risk process, and should be done as infrequently as possible. This requirement is not audited in facilities that are dedicated to gluten-free production.*

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- *Example Evidence: Written production schedules that address sequencing of gluten-free and gluten-containing production. Observation that sequencing schedule is followed.*

49. **The Gluten Program must include procedures for, at a minimum, an annual review of possible sources of carryover or cross-contact between product lines in those plants producing both gluten-containing and certified gluten-free Products.**
    - *Rationale: In mixed-use facilities, any changes in production schedules, staff, equipment, or processes can affect the gluten status of the finished product. Plant management should regularly review their production processes to make sure that the Gluten Program has not been affected by any changes to operations.*
    - *Example Evidence: Scheduled review of policies and procedures, observation that written procedures are reviewed and updated, meeting notes or minutes where management has discussed changes to operations and their effect on the Gluten Program.*
50. **If packaging occurs on a separate line from production, the Gluten Program must include procedures for sequencing packaging activities and cleaning packaging facilities and equipment between lots in order to eliminate carryover or cross-contact.**
    - *Rationale: Mislabeling and mispackaging are the most common causes of gluten and allergen recalls. If packaging is done separately from production, then the sequencing and cleaning requirements that apply to production must also be present for the packaging operations.*
    - *Example Evidence: Documentation of packaging and label review, either within the batch record review or as a separate review step. Evidence that staff are aware that packaging/labels must be reviewed for each packaging run. Written procedures for cleaning packaging equipment between gluten-containing and gluten-free runs that have been validated and are regularly verified or re-validated. Documentation of cleaning packaging equipment and any verification activities.*
51. **The Gluten Program must include a requirement for inspecting storage areas and outgoing shipping containers/trucks that are used for certified gluten-free Products, to ensure they are clean and do not present a risk of gluten cross-contact. Records of these inspections must be maintained.**
    - *Rationale: The plant must ensure that their warehouse and the trucks that distribute their finished products are not a source of gluten contamination.*
    - *Example Evidence: Written procedure for warehouse and outgoing truck checks. Documentation that these checks are occurring. Observation that employees understand how to perform the checks. Observation that the shipping area is free of gluten contamination.*
52. **The Gluten Program must include a requirement that prohibits the use of reworked, recycled, or reclaimed materials from gluten-containing production in the manufacturing of certified gluten-free Products. In addition, there must be a written procedure for the rework, recycling, or reclaiming of any certified gluten-free Product into another certified gluten-free Product.**
    - *Rationale: In plants that use reworked, reclaimed, or recycled materials among certified Products, procedures must be in place to ensure that rework is not a potential source of gluten contamination and that all such materials can be traced.*

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Examples of these types of materials might be fryer oil used to make tortilla chips, or enrobing chocolate that is collected and re-used. If the plant does not allow reworked, reclaimed, or recycled materials, there should be a written procedure stating this.

- *Example Evidence: Written procedure for handling and tracking reworked, reclaimed, or recycled materials, including a prohibition on using these materials from gluten-containing production in gluten-free production. Observation that these materials are tracked on batch records. If reworked, reclaimed, or recycled materials are not used in the plant, a written statement that prohibits the use of these types of materials.*

53. **The Gluten Program must include procedures for handling waste materials from production.**
    - *Rationale: Procedures must be in place to ensure that waste materials from production are not a potential source of gluten contamination.*
    - *Example Evidence: Written procedure for handling waste materials from production. Observation that waste is being handled according to the procedure, and that waste handling procedures do not present a risk of gluten contamination.*
54. **The Gluten Program must include validated procedures and defined materials to be used for purging between production runs, and for the use or disposal of purge materials if purging is used in the plant. The procedure must include either the required purge time or purge volume that results in an effective purge. If purging is not used as a cleaning method, the Gluten Program must include a requirement that prohibits the use of purging for equipment cleaning.**
    - *Rationale: Plants that use purging to clear equipment between gluten-containing and gluten-free production must have written, validated purge processes that define acceptable purge materials, purge time or volume, and how to dispose of purge material.*
    - *Example Evidence: Written procedure for purging that includes acceptable materials, purge time or volume, and disposal. Observation that purge process is verified or re-validated regularly. Evidence that staff are aware of purge procedures. If purging is not used, a written requirement that purging cannot be used as a cleaning method.*
55. **The Plant must assess the risk of gluten cross-contact from dust, and implement appropriate dust control measures as needed.**
    - *Rationale: Gluten-containing airborne dust can present a risk to gluten-free production. The plant must assess whether they generate gluten-containing dust, and if so, there must be processes in place to prevent it from contaminating gluten-free product.*
    - *Example Evidence: Documentation of a risk assessment on the risk of gluten cross-contact from dust, and if needed, a written procedure for dust control. Observation that dust is controlled in the plant. Validation data demonstrating that no risk is presented by airborne dust if no control measures are in place.*
56. **The effectiveness of the Gluten Program must be evaluated annually, at a minimum, and records of this must be retained between evaluations.**
    - *Rationale: Plants producing certified product must demonstrate that their Gluten Plan is effective in mitigating risks to gluten-free production.*

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- *Example Evidence: Documentation of a review of data that would indicate the effectiveness of the Gluten Program over the past year, such as verification testing data on finished products, records of contamination incidents, or consumer complaints.*

57. The Gluten Program records must allow for all Products to be traced forward to the first immediate customer, and back to each individual ingredient lot and supplier.

- *Rationale: Manufacturers must be able to take any of their products and identify every ingredient used in it as well as every location where it is shipped, in order to be able to investigate any contamination incidents.*
- *Example Evidence: Batch records that include specific ingredient names/lot numbers; outgoing shipping records for all products.*

Instances of Cross-Contact or Suspected Cross-Contact:

58. The Gluten Program must contain a general Corrective Action procedure for any instances of cross-contact or suspected cross-contact, including methods of root cause analysis, methods of reporting the corrective action, and methods for determining the effectiveness of any action taken.

- *Rationale: Appropriate corrective action procedures are essential for investigating contamination incidents as well as for continual improvement of operations.*
- *Example Evidence: A written corrective action procedure that includes root cause analysis, proposed solutions, and review of effectiveness. Documentation of corrective actions.*

59. The Gluten Program must include specific procedures for dealing with reports of suspected gluten contamination coming from customers or other parties. Any such complaints must be documented and records of the investigation and corrective actions taken must be maintained.

- *Rationale: Plants must be able to respond appropriately to consumer complaints, and complaint tracking and review is an essential part of the continual improvement process.*
- *Example Evidence: A written process for handling complaints. Records of complaints and any corrective actions that have resulted from them. Evidence that staff know how to handle and document complaints.*

60. The Gluten Program must include specific procedures for handling incoming gluten-free raw materials that are found to contain gluten.

- *Rationale: Plants need to have clear instructions for handling incoming raw materials that are found to be contaminated with gluten in order to avoid accidental use of those materials or the potential of cross-contamination from those materials. Can be part of a general procedure on handling out of specification raw materials.*
- *Example Evidence: A written process for handling raw materials that are found to be contaminated with gluten. Documentation of the disposition of any contaminated raw materials. Evidence that staff clearly understand how to handle contaminated raw materials.*

61. The Gluten Program must include specific procedures for handling gluten contamination of facilities, equipment, or work tools.

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- *Rationale: Plants need to have clear instructions for dealing with facilities, equipment or work tools used in gluten-free production that are found to be contaminated with gluten in order to avoid their accidental use or the potential of cross-contamination.*
- *Example Evidence: A written process for dealing with facilities, equipment, or work tools used in gluten-free production that are found to be contaminated with gluten. Documentation of any instances of contaminated facilities, equipment or work tools being used in gluten-free production, along with any resulting corrective actions. Evidence that staff clearly understand how to handle contaminated facilities, equipment, or work tools used in gluten-free production.*

62. **The Gluten Program must include specific procedures for handling gluten-contaminated product that have not yet left the plant, including a requirement that GFCO be notified at gfco.alerts@gluten.org in the event of any result that indicates a level of gluten greater than the GFCO definition of Gluten-Free in a Product.**
    - *Rationale: Plants need to have clear instructions for handling finished product that is found to contain gluten at a level greater than the Applicable Gluten Free Threshold, in order to avoid the accidental release of this product for sale.*
    - *Example Evidence: A written process for dealing with a finished product that contains glute at a level above the Applicable Gluten Free Threshold, which includes notifying GFCO. Documentation of any instances of contaminated finished product, along with any resulting corrective actions. Evidence that staff clearly understand how to handle contaminated finished product.*
63. **The Gluten Program must include specific procedures for handling instances of mislabeling or mispackaging of products.**
    - *Rationale: Plants need to have clear instructions for handling finished product that are mislabeled or mispackaged in order to avoid the accidental release of this product for sale.*
    - *Example Evidence: A written process for dealing with the finished product that is mislabeled or mispackaged. Documentation of any instances of mislabeled/mispackaged finished product, along with any resulting corrective actions. Evidence that staff clearly understand how to handle mislabeled/mispackaged finished product.*
64. **The Gluten Program must include specific procedures for handling instances of gluten contamination discovered in product sent to customers or on the open market (recall plan), including a requirement that GFCO be notified of any potential or actual market withdrawal or recall of a certified Product at gfco.alerts@gluten.org.**
    - *Rationale: The plant must have a process for handling recalls and withdrawals, and verify the effectiveness of this process.*
    - *Example Evidence: A written recall procedure that includes notifying GFCO. Documentation of any actual recalls, or of a mock recall performed successfully within the past year.*

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Product and Ingredient Testing

65. **The test methods used by the Plant, Brand Owner, or their chosen 3rd party laboratory must be fit-for-purpose for the ingredients or products certified and must be methods that have undergone independent validation through AOAC or AACCI, or that have been otherwise approved by GFCO.**
    - *Rationale: Only properly validated gluten test methods can be used for validation and verification activities.*
    - *Example Evidence: Observation that the plant is using a GFCO Approved Test Kit. Evidence that the plant has a copy of the GFCO Approved Test Kit list. Observation that the plant has documentation allowing them to use a kit not listed on the GFCO Approved Kit List.*
66. **Independent 3rd party laboratories used for product or ingredient testing should be accredited to ISO 17025 for gluten testing using a suitable method as defined above.**
    - *Rationale: Any outside labs used for validation or verification purposes should be accredited to ISO 17025 or meet the essential criteria of ISO 17025 as established by GFCO.*
    - *Example Evidence: Observation of an accreditation mark on any test results received from outside laboratories. Observation that outside laboratories are using test methods listed on the GFCO Approved Kit List. Documentation that GFCO has approved the use of any lab that is not accredited to ISO 17025.*
67. **Both independent and Plant-operated laboratories must perform the testing as the method was validated, and any deviations from the published validated method must be reported.**
    - *Rationale: Gluten test methods have been validated according to the manufacturer's instructions, and any alteration to the provided test method may invalidate the results. The plant or laboratory must report any changes to the test method so they can be considered when evaluating the results.*
    - *Example Evidence: Written testing procedures that match the instructions for the test kit. Documentation of any alterations to the test method. Observation that staff know how to perform the test method as described by the kit manufacturer.*
68. **If there is not a suitable test method as defined above, the ingredient or product must undergo a matrix validation for a chosen method using a validation protocol approved by GFCO. This validation may be performed by any ISO 17025 accredited laboratory.**
    - *Rationale: In the event that no suitable commercial test method is available for the plant's products, the plant may choose to develop their own test method or one developed by an outside laboratory. This method would need to undergo a validation as assigned by GFCO.*
    - *Example Evidence: Documentation of the approval of an alternative test method by GFCO.*
69. **The Plant or Brand Owner must test their raw materials or products according to the schedule and sampling plan determined by GFCO and written in the most recent audit report. Testing records must be maintained that justify the use of the step-down schedule or validation plans described in the GFCO Manual.**

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- *Rationale: GFCO assigns testing of raw materials, equipment, and finished product based on a risk analysis, and the plant/brand owner must comply with their contractual testing requirements in order to maintain certification.*
- *Example Evidence: Test logs, records, or reports that cover all of the raw materials, equipment, and finished products that are required to be tested according to the certification contract.*

70. **The Plant or Brand Owner must submit all test results to testing@gluten.org at the end of each calendar quarter.**
    - *Rationale: The plant or brand owner is contractually obligated to submit their testing results to GFCO each calendar quarter for review. This includes all ingredient, equipment and finished product testing.*
    - *Example Evidence: Receipt of test logs, records, or reports that cover all of the raw materials, equipment, and finished products that are required to be tested according to the certification contract.*
71. **All Plants and Brand Owners performing testing in their own facility must have documentation of the training of the employees performing the tests, including annual competency testing.**
    - *Rationale: The safety of certified gluten-free products is verified on-site by those plants that perform their own testing, so it is essential that plant personnel are properly trained to perform the tests, and their performance is reassessed at least annually.*
    - *Example Evidence: Training materials and training records for staff members performing gluten testing. Documentation of an assessment of their competency within the last year, such as their performance testing blind samples. Observation that plant personnel are performing the tests correctly.*
72. **All Plants and Brand Owners performing testing at their own facility must participate in a Proficiency Testing scheme for gluten at least every 4 years, provided by a 3rd party or administered by GFCO.**
    - *Rationale: Proficiency testing is an independent measure of the plant's ability to perform and report their gluten test results correctly, and is necessary for providing confidence in the testing data generated by the plants.*
    - *Example Evidence: Documentation of successful participation in a proficiency testing scheme for gluten within the past 4 years.*
73. **Any confirmed, unexpected positive testing results that exceed the gluten level of the GFCO definition of Gluten-Free from external or internal testing will require a documented Corrective Action investigation.**
    - *Rationale: Any positive gluten test results in a certified finished product must be investigated through the plant's corrective action process since these results will always be unexpected.*
    - *Example Evidence: Corrective action reports on any positive gluten results in certified finished product that include root cause analysis and a proposed solution. Evidence that the proposed solution was implemented and is being monitored.*
74. **Failed Proficiency Testing rounds will require a documented Corrective Action investigation.**
    - *Rationale: If the plant does not obtain the expected results during proficiency testing, they will need to examine the source of the error.*

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- *Example Evidence: Corrective action reports on any failed proficiency testing results that include root cause analysis and a proposed solution. Evidence that the proposed solution was implemented and is being monitored.*

Surveillance

75. **If the product being certified is not commercially available, the Plant must allow auditors or agents of GFCO to collect surveillance samples, or provide samples to GFCO on request.**
    - *Rationale: Finished product surveillance is an important part of GFCO certification, so plants must make product available for testing by GFCO.*
    - *Example Evidence: Collection of test samples by auditors or GFCO staff or representatives.*

Improvement

76. **The Plant must show evidence of continual improvement of their gluten program through an annual review with management.**
    - *Rationale: Plant management must be committed to continually improving the Gluten Program. This can be achieved through a review of the program's policies and procedures or other meetings or reviews of the program.*
    - *Example Evidence: Meeting minutes, agendas, or notes documenting management review of the program. Evidence of review and revision of policies and procedures based on corrective or preventive actions.*
77. **The Plant must conduct annual mock recalls with a goal of tracing 100% of a chosen product within a timeframe determined by the plant. This exercise does not have to be performed on a certified Product. The Plant must evaluate the results of these exercises and perform any needed corrective action investigations. The results of this internal audit must be recorded, and records of each mock recall must be retained for a minimum of 12 months.**
    - *Rationale: In the absence of any actual product recalls, the plant must perform mock recalls to validate the effectiveness of their recall plan.*
    - *Example Evidence: Mock recall report completed within the past year. Documentation of any corrective actions that resulted from an incomplete or slow mock recall exercise.*
78. **The Plant must conduct annual internal audits that include the requirements of their Gluten Program and this Standard. These audits must be performed by trained personnel who have been determined to be competent for this task by the Plant. No internal auditor may audit their own work. If these audits demonstrate any deficiencies in their policies, procedures, or programs related to gluten-free production, the Plant must initiate appropriate corrective action investigations. The results of this internal audit must be recorded, and records of each internal audit must be retained for a minimum of 12 months.**
    - *Rationale: Internal audits are essential for continual improvement. Internal audits performed by the plant should cover all relevant GFCO Standard requirements. Any non-conformances found during the internal audit must be addressed through the plant's corrective action process.*

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- *Example Evidence: Internal audit reports completed within the past year that address the GFCO Standard requirements. Documentation of corrective actions for any audit non-conformances or deficiencies. Training records for internal auditor(s).*

Use of the Certification Mark

79. **The Plant and Brand Owner must only use the GFCO certification mark on Products that meet the GFCO definition of Gluten-Free, are listed on a current, valid certificate issued by GFCO, and in the manner defined in the current GFCO Branding Standard.**
    - *Rationale: The GFCO certification mark can only appear on products that are reviewed and approved by GFCO, and that appear on the certificate.*
    - *Example Evidence: Packaging bearing the GFCO logo. No products bearing the logo that are not on the certificate. Use of the logo according to the GFCO Branding Standard.*
80. **The use and format of the GFCO certification mark on the certified Product's packaging, advertisements, or other printed materials must be approved in advance by GFCO.**
    - *Rationale: GFCO must review and approve all uses of the GFCO logo/certification mark.*
    - *Example Evidence: Documentation of GFCO approval for all packaging proofs, advertising, marketing materials, etc. bearing the GFCO logo.*

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Annex A - GFCO Fee Schedule

GFCO certification fees are determined by company size and inherent product and ingredient risk. The table below can be used to determine the annual fee and audit costs for any company. Risk levels are determined by an internal GFCO algorithm, and will be available only after receipt of a completed certification application and a list of all products (and their ingredients/components) being submitted for certification. All prices are in U.S. Dollars.

Company Size	Low Risk	Med Risk	High Risk	# of Plants	Net Sales
Micro Enterprise (9 or fewer employees, unlimited products)	$1650	$2200	$3300	1-5	
	$2200	$2750	$4400	6-10	
	$2750	$3300	$5500	11+	
Small Business (10 - 49 employees, unlimited products)	$1980	$2750	$3850	1-5	
	$2530	$3300	$4950	6-10	
	$3080	$3850	$6050	11+	
Medium Business (50 - 249 employees, unlimited products)	$2310	$3300	$4400	1-5	
	$2860	$3850	$5500	6-10	
	$3410	$4400	$6600	11+	
Large Business (250+ employees, unlimited products)	$4400	$5500	$6600	1-5	<500M
		$6050	$7700	1-5	0.5-1B
		$7150	$8800	1-5	>1B
	$5500	$6600	$7700	6-10	<500M
		$7150	$8800	6-10	0.5-1B
		$8250	$9900	6-10	>1B
	$6600	$7700	$9350	11+	<500M
		$8250	$11000	11+	0.5-1B
		$9350	$13200	11+	>1B

Licensing Agreements**	
Individual (per Brand Owner)	Bundle (up to 5)*
$1100	$2750

*Contact GFCO about larger licensing bundles

**Licensing agreements are required when a manufacturing facility that holds a full certification contract wishes to manufacture a certified product under a brand that they do not own. This may occur with private label or contract manufacturing. A licensing fee is assessed for each connection between a brand owner and a manufacturing facility. This fee may be paid by either the brand owner or the manufacturing facility according to the arrangements made in the licensing agreement.

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Annex A – GFCO Fee Schedule (continued)

Auditing Costs (same for all company sizes and risk levels)	
Pre-Assessment Audit Fee	$700
Certification Audit Fee	$700 plus all travel expenses
Rush Fee (if available)	Additional $1000/facility plus $2000 estimated travel expenses
Estimated Travel Cost Domestic (within the U.S.)	$400 per facility
Estimated Travel Cost International	International Travel Cost Estimates are based on a quote from the auditor.

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Revision History:

GFCO Manual Rev 2024 Summary of Changes

Cover page:

Replaced B&W GIG logo with registered GIG mark

Updated revision number from 2023 to 2024

Updated Last Amended date to 240601

Page 2:

Changed reference to 2020 Standard to reflect the updated 2024 Standard

Page 6:

Ingredient definition, added the phrase ”in the form that it is received by the Plant”

Added a definition of Ingredient Risk Factor

Under the definition of Manufactured Material, added an additional example which reads “Another example would be a pre-blended baking or flour mix (cake mix, bread mix, etc.).”

Page 7:

Added a definition of Plant Registration

Page 8:

Updated the certification process flow chart, and added the reminder statement at the bottom.

Page 9:

Under the header Preparing to Apply for Certification, second paragraph, removed the last sentence which read “Wherever possible the prospective Plants should request vendor statements, GFCO certificates or proof of lot-specific testing from their ingredient suppliers to reflect the gluten-free status of their raw materials.” A later section in the Manual now provides more detailed information on expected ingredient documentation.

Under the header Preparing to Apply for Certification, added the third paragraph which is a section on *Consultancy*.

Paragraph under Certification Scope header, second sentence changed from “GFCO certification is specific to a Product made at a single Plant or set of Plants.” to “GFCO certification is specific to a Product made under a specific Brand at a single Plant or set of Plants.”

Also added the second paragraph under Certification Scope which reads “GFCO confines its certification requirements, evaluations, reviews, decisions, and surveillance activities to matters specific to the appropriate Certification Standard and other criteria required for product certification.”

Page 10:

Table at bottom of page, changed fifth line from “Responsible for submitting Product & Ingredient updates” to “Responsible for updating and managing product and ingredient submissions to GFCO”, and made that only applicable to the Certification Contract holder.

Page 11

Second paragraph changed from “Because a Certification Contract is required in order for a Brand Owner or Plant to receive a copy of the yearly audit reports, the GFCO program allows both parties to hold a Certification Contract if that is the best business decision for them.” to “Because a Certification Contract is required in order for a Brand Owner or Plant to submit Products and Ingredients, and receive a copy of the yearly audit reports, the GFCO program allows both parties to hold a Certification Contract if that is the best business decision for them.”

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New section added titled “Campus locations”. This replaces the previous section under Audited Plants that explained how separate Plants can be combined under one audit. The previous section read:

> Separate Plants can be combined under one audit if they meet all of these criteria:
>
> 6. The Plants operate under the same management system (policies and procedures).
> 7. The same plant manager(s) manage the Plants, which are close enough together to make this feasible.
> 8. The Plants perform identical manufacturing processes, or steps in a continuous process.

The new section reads:

> Campus Locations
>
> After the initial auditing of each production/packaging site, at the request of the client GFCO may conduct a review to determine if separate Plant addresses can be combined into one location for the purposes of auditing in subsequent years. This type of combined site will be referred to as a Campus location. The primary criteria that GFCO will review to determine if Plants can be combined into a Campus are:
>
> 1. Whether the Plants operate under the same management system (policies and procedures).
> 2. Whether the same plant manager(s) manage the Plants
> 3. Whether the Plants are close enough together to be considered a Campus (generally within walking distance)
> 4. Whether the Plants perform identical manufacturing processes, or steps in a continuous process (e.g. manufacturing products in one building that are then packaged in another)
> 5. Feedback from our auditors on whether the Plants can all be adequately audited within the audit timeline
>
> These criteria will be reviewed internally by a GFCO Manager, who will make a determination on combining the Plant locations under one annual audit.

Page 12:

Under the Audited Plants heading from the previous page, the first paragraph that previously read “If a Manufactured Material or a high-risk Ingredient that is not certified by GFCO makes up greater than 20% of the Product by weight, the Supplier may be required to be a registered and approved plant with that material listed on their GFCO certificate. An example of this might be a frozen spaghetti dinner Product where the applicant buys the gluten free pasta from a Supplier and lists it as an Ingredient. Because gluten free pasta meets the definition of a Manufactured Material, makes up greater than 20% of the Product by weight, and is high-risk (see Definition of Ingredient Risk Levels below), this Product could not be certified unless the Plant making the pasta registered with GFCO and was approved to manufacture by GFCO.” **Has been replaced by the following paragraph**: “In certain cases, GFCO may require that pre-made, multi-component ingredients (Manufactured Materials) are also certified by GFCO, which would entail the addition of the supplier’s plant to a certification contract and annual audits of their facilities. See the section below on Product and Ingredient Review for details of when this might be required.” The details of Manufactured Materials have been moved into the section on The Product and Ingredient List.

Second paragraph under The GFCO Application, first sentence changed from “The application will require the submission of a Product and Ingredient List.” to “The application will require the submission of a complete list of the applicant’s proposed Products and their related Ingredients.”

Under The GFCO Application header, fifth paragraph, second and third sentences changed from “If the applicant does not continue through the certification process within this timeframe, GFCO will confidentially destroy these documents. The applicant will need to submit new documents to begin the certification process again.” to “If the applicant does not continue through the certification process within this timeframe, GFCO will confidentially delete these records. The applicant will need to resubmit their information to begin the certification process again.”

Under The Product and Ingredient List Header, beginning of first sentence changed from “As part of the certification application, GFCO will require each applicant to submit a list of every Product that will be submitted for certification…” to “As part of the certification application, GFCO will require each applicant to submit a list of every Product that will be seeking certification…”

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Page 13:

Second full paragraph was removed, which read “Every lot of an Ingredient with a risk factor of 3 or 4 must be tested prior to use in certified Product. If the applicant has vendor statements regarding the gluten-free status of an Ingredient, proof of ongoing lot-specific gluten testing done by the vendor, or a copy of a vendor’s GFCO certificate, they should submit these with the Product & Ingredient list. GFCO can provide a vendor statement template. These documents can reduce the risk of Ingredients and reduce the testing requirements for the Plant.” This information has been added to point 11 under the section on Product and Ingredient Review.

New section titled Product and Ingredient Review was added.

Page 15:

First sentence under The Certification Quote section changed from “Once the GFCO Certification Application has been reviewed and approved, the GFCO Account Representative assigned to the applicant can provide a Certification Quote.” to “Once the GFCO Certification Application has been reviewed and approved, GFCO can provide a Certification Quote.”

Page 19:

Under section titled The Certification Contract, added “Annual Plant Registration” to the list of requirements for maintaining certification

Page 20:

Under Maintaining Certification, second point in first bulleted list changed from “Yearly surveillance facility audits (performed by the GFCO certification body)” to “Yearly surveillance audits”

Added “Annual Plant registration” to the list of requirements under *Maintaining Certification*.

Under Packaging Approval and Use of the GFCO Logo, first sentence, added the phrase “by submitting proofs/images to gfco.branding@gluten.org”

Page 24:

Under Ingredient Testing, final paragraph, final sentence changed from “GFCO may request updated versions of outdated documents in order to continue the approval or risk reduction of ingredients.” to “GFCO will request updated versions of outdated documents in order to continue the approval or risk reduction of ingredients.”

Page 27:

Under point 4.a., changed the beginning of the first sentence from “If all of the 3rd party lab results are positive…” to “If all of the third-party lab results are greater than the Applicable Gluten-Free Threshold…”.

Under point 4.b., changed the first sentence from “If the results from the additional tests are above and below the Applicable Gluten-Free Threshold, then we will determine the mean plus the laboratory’s measurement uncertainty (or 2x the standard deviation, whichever is greater).” to “If the results from the additional tests are above and below the Applicable Gluten-Free Threshold, then we will determine the mean plus two standard deviations.”

Page 29:

Under Product Removals and Additions, first paragraph, first sentence changed from “During the period that a plant holds a current registration and certification, they may add or remove Products from the certificate by sending a request, using a template provided for this purpose.” to “During the period that a Plant or Brand Owner holds a valid Certification Contract, they may add or remove Products from the certificate by submitting an updated list of Products to GFCO.”

Page 31:

Added the section on Outsourcing.

Under Public Information header, second paragraph, first sentence changed from “Any Plant that holds a fully executed Certification Contract will appear on the GFCO Manufacturer Listing, unless the plant has indicated, at the

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time of registration, application or through written (email or mail) communication to GFCO, that they do not wish to appear on the public list." to "Any Plant that holds an active Certification Contract will appear on the GFCO Manufacturer Listing, unless the plant has indicated, at the time of registration, that they do not wish to appear on the public list."

Page 32:

First paragraph after first bulleted list was changed from "To request that Plant information be removed from the public list, contact GFCO via email at gfco.branding@gluten.org, or by mail to GFCO, 730C Commerce Center Drive, Sebastian, FL 32958." to "To request that Plant information be removed from the public list, contact GFCO via email at gfco.clientsupport@gluten.org."

Under Auditor Qualifications, first paragraph and bulleted list changed from:

> "In order to serve as a contracted auditor for the GFCO Product certification program, prospective auditors must meet the following minimum requirements:
>
> - At least 2 years of experience in a food safety, quality, regulatory or auditing environment.
> - Successful completion of auditor training to the GFCO certification standard."
>
> to
>
> "Prospective auditors must meet the following requirements to serve as a contract auditor for the GFCO product certification program:
>
> - A minimum of 2 years' experience in a food safety, quality, regulatory or auditing environment.
> - Successful completion of auditor training to the GFCO certification standard."

Under Auditor Qualifications, second paragraph, first sentence changed from "All new auditors, and every auditor once per year, will participate in GFCO Auditor Training" to "All new and current auditors participate in annual GFCO Auditor Training."

Page 35:

Under Withdrawal, fifth paragraph, end of last sentence changed from "…GFCO will require response and resolution within 5 days." to "…GFCO will require response and resolution within 10 days." [This change was made to align with our current contract template]

Page 36:

Header "The Use of ICT in GFCO Certification" changed to "The Use of Information and Communications Technology (ICT) in GFCO Certification"

Page 41:

Under Appeals, first paragraph, the following sentence was added: "The purpose of the appeal is to determine whether GFCO policies were correctly applied in a specific instance."

Under Impartiality / Responsibilities, first paragraph, second sentence changed from "The GFCO Program Manager and GFCO Quality Control Manager are responsible for training certification personnel and auditors of possible sources of conflict and the requirements for maintaining impartiality." to "GFCO Managers are responsible for training certification personnel and auditors of possible sources of conflict and the requirements for maintaining impartiality."

Page 42:

Deleted section on Dispute Resolution

Page 44:

Under Additional Information, removed the section on Products and Ingredients Requiring Special Consideration. Pertinent parts of this information have been moved under *Product and Ingredient Review.*

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Under *Sampling for Ingredients with Large Particle Size or Relative Heterogeneity*, fourth full paragraph, third sentence, changed “Reduce each sample to 100g…” to “Reduce each sample to 500g…”.

Page 46:

For GFCO Standard updates, please see www.gfco.org/standard-update

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