GFCO Certification Scheme Manual

Rev. 2020

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 released the GFCO Standard rev. 2016 on March 30, 2016, and it went into effect on July 1, 2016. This Standard gives GIG's requirements for GFCO gluten-free certification.

The GFCO Standard defines the manufacturing practices required to certify Gluten-Free food, beverage, nutritional/supplement and personal care Products, and to use the GFCO logo on those products.

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

Applicants should consult their chosen certification body for their specific processes for GFCO gluten-free product certification.

Any changes to the policies and requirements in this document will be communicated to all GFCO-approved certification bodies and 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

Brand Owner: A Legal Entity that owns the brand name of the Product. 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.

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 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 are 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

Full Certification: 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 Full Certification, and take responsibility for all of the GFCO requirements for Product certification.

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.

Gluten-Free: The presence of gluten at 10 parts per million (“ppm”) or less, or 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). 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.

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

Lot: Any set of products manufactured from the same pull or staging of ingredients. For example, if your sausage Plant pulls 300 lbs. of chicken from refrigeration, and enough

seasonings and casings to run 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 would indicate the start of a new lot.

Manufactured Material: Any material used in 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. 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.

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.

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.

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.

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, 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”.

Applying for Certification

GFCO Standard Training

It is a great idea to learn about the GFCO Standard and safe gluten-free production before applying for product certification. Training is available through:

- Training courses provided by GFCO
- Self-training 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 GFCO before a product certification application is submitted. Plants can register on the GFCO website (www.gfco.org/plant-registration).

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 Certification 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 should 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. 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.

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 at a single Plant or set of Plants. Each Plant must comply with the GFCO Standard requirements, including the GFCO gluten threshold of 10 ppm or less in certified products and their ingredients. Plants that are primary grain processors, or who sell whole intact unprocessed grains, beans, seeds pulses or legumes, must also meet the 0.25 gluten-containing grain/kilogram threshold as determined by visual examination of the product.

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 by a GFCO-approved certification body. Each Plant will receive a separate audit and audit report. Separate Plants can be combined under one audit if they meet all of these criteria:

1. The Plants operate under the same management system (policies and procedures).
2. The same plant manager(s) manage the Plants, which are close enough together to make this feasible.
3. The Plants perform identical manufacturing processes, or steps in a continuous process.

If a Manufactured Material or a high-risk Ingredient that is not certified by GFCO makes up a large percentage of the Product, the Supplier may be required to be a registered and approved plant. 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 a large part of the Product, and is high-risk (see Definition of Ingredient Risk Levels below), this Product could be certified unless the Plant making the pasta registered with GFCO and was approved to manufacture by a certification body.

In Rental Kitchens, each Company that wants to make Product 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 registration that applies to other manufacturers working there.

The Product and Ingredient List

As part of the certification application, each GFCO-approved certification body will require each applicant to submit a list of every Product that will be submitted for certification, and all of the Ingredients that will be used to make those Products.

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.

The Ingredient list must show all of the components of every multi-component ingredient, and must include processing aids.

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. If Product certification is granted, the applicant will receive a copy of their Product and Ingredient list with risk factors for each ingredient.

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.

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.

Choosing a Certification Body

Once a Plant is registered with GFCO, it can apply for Product certification through a GFCO-recognized certification body, or another Brand Owner may apply to work in that Plant. All certification bodies recognized by GFCO must be accredited to ISO/IEC 17065, as determined by an ILAC recognized accreditation body.

The applicant must maintain a contract with the certification body that covers their GFCO certification services, including the audit scope, audit reporting requirements, the certification body's fee structure, the conditions for reduction, suspension, probation or withdrawal of certification, and the certification body's appeals and complaints processes.

Recognized GFCO certification bodies are:

- GFCO
- Control Union
- SCS Global Services

Links to GFCO-recognized certification bodies are available on the GFCO website (www.gfco.org/certification-bodies).

The certification body will select trained GFCO auditors to perform a facility audit, and will arrange the audit schedule with the Plant.

It is the responsibility of the certification body to ensure that the Plant is meeting all GFCO Standard requirements, and that the audit reports are complete and accurate.

The certification decision will be made by the certification body based on the evidence of compliance found during the audit, and the resolution of any non-conformances. The certification decision must be made within 15 days of the resolution of all audit non-conformances.

The Audit and Audit Report

GFCO audits are conducted using a checklist provided by GFCO to the certification bodies. This is done to ensure that all applicants are audited using the same format and requirements.

The Plant does not need to be in active production on the day of the audit, but all equipment and facilities must be in place, as they will be used to make certified Products.

The certification body must make the audit report available to the Plant within 10 business days of the audit.

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

The audit report is the property of the certification contract holder, and cannot be distributed to other parties without permission.

Audit Non-Conformances

If the auditor identifies any non-conformances during the audit, they must provide the Plant with a description of the non-conformance and identify the relevant requirement from the GFCO Standard.

All non-conformances must be addressed within 60 days of the audit date.

The Certificate

The final certificate will be issued based on the decision of the certification body and GFCO's review of the Products and Ingredients submitted for certification. Regardless of the certification decision made by the certification body, GFCO maintains the right to remove individual Products from the certification if, upon review, they are not appropriate for gluten-free certification.

The certificate will be provided within 10 calendar days of notification of the certification decision by the certification body, along with electronic copies of the GFCO logo for use on the packaging for Products that appear on the certificate.

Regardless of the certification decision made by the certification body, or the approval of a manufacturing facility, no Product may be considered to be certified, or bear the GFCO logo, until it appears on a Product certificate issued by GFCO.

Licensing Agreements

A Licensing Agreement is a contract that allows a Brand Owner other than the registered Plant to use the GFCO logo on their Products. A Licensing Agreement can only occur when the Plant(s) manufacturing the product are currently registered with GFCO and are listed on a full certification contract issued through a GFCO-approved certification body.

The Licensing Agreement provides the Brand Owner with the requirements for 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 Full Certification contract. Licensing Agreements are only issued by the GFCO Scheme, not by any outside certification body.

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 annual surveillance audits by the certification bodies, and through review of records submitted to directly to the GFCO Scheme:

- Submission of packaging proofs and other logo use for approval (send to branding@gluten.org)
- Annual surveillance facility audits (performed by your chosen certification body)
- 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 finished Product, made directly to GFCO at gfco.alerts@gluten.org.

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 un-register and then re-register and re-apply with a certification body at a later date. There is no “hold” status for certification.

Packaging Approval and Use of the GFCO Logo

The display of the GFCO “GF” Logo on any product packaging or print/digital media must be reviewed and approved by GFCO prior to use. 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. Current clients may also request a copy of the Branding Standard at any time.

The applicant will receive logo files for designing their packaging once certification has been granted. In some circumstances 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 and the certification body assume no responsibility for monetary loss if packaging is designed or printed prior to the issuance of a certificate. The applicant will need to sign an agreement with GFCO to receive the logo files 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.
c. Any other statements or claims that would contradict the use of the GF logo or cause confusion for consumers.

If changes are needed, 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 annually for compliance with the GFCO Standard, by their chosen certification body. 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.

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

Finished Products

Each company holding a Product certification is responsible for ensuring that finished 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 finished Product testing based on their inherent risks. Testing data must be submitted to testing@gluten.org at the end of every calendar quarter, regardless of the certification body that the Plant or Brand Owner uses.

The annual audit report will always provide the highest, baseline level of finished product testing that is expected from a Plant. Plants that have a documented history of testing with no positive test results in finished product have the option of decreasing their finished product testing level according to the following schedule. Plants that have a confirmed positive (>10 ppm) gluten result in finished 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 finished products:

- **If your assigned testing calls for testing multiple samples from the beginning, middle and end of each production lot of certified product:**
    - After six months or 20 consecutive production runs of GFCO certified products (whichever is longer) with no positive (>10 ppm) gluten results in finished product, this may be reduced to one sample from each production lot of certified product.
    - After one year or 40 consecutive production runs of GFCO certified products (whichever is longer) with no positive gluten results in finished product, this may be reduced to one certified product per day that you are manufacturing certified product(s).
    - After 18 months or 60 consecutive production runs of GFCO certified products (whichever is longer) with no positive gluten results in finished product, this may be reduced to one certified product during each week that you are manufacturing certified product(s).
    - After 2 years or 80 consecutive production runs of GFCO certified products (whichever is longer) with no positive gluten results in finished product, this may be reduced to one certified product during each month that you are manufacturing certified product(s).
    - After 30 months or 100 consecutive production runs of GFCO certified products (whichever is longer) with no positive gluten results in finished product, this may be reduced to one certified product during each calendar quarter that you are manufacturing certified product(s).
    - If at any point a finished product tests positive for gluten at >10 ppm, the plant must return to its most recently assigned testing requirement level and begin this schedule again.
- **If your assigned testing calls for testing one sample from each production lot of certified product:**
    - After six months or 20 consecutive production runs of GFCO certified products (whichever is longer) with no positive gluten results in finished

product, this may be reduced to one certified product per day that you are manufacturing certified product(s).
    - After 1 year or 40 consecutive production runs of GFCO certified products (whichever is longer) with no positive gluten results in finished product, this may be reduced to one certified product during each week that you are manufacturing certified product(s).
    - After 18 months or 60 consecutive production runs of GFCO certified products (whichever is longer) with no positive gluten results in finished product, this may be reduced to one certified product during each month that you are manufacturing certified product(s).
    - After 2 years or 80 consecutive production runs of GFCO certified products (whichever is longer) with no positive gluten results in finished product, this may be reduced to one certified product during each calendar quarter that you are manufacturing certified product(s).
    - If at any point a finished product tests positive for gluten at >10 ppm, the plant must return to its most recently assigned testing requirement level and begin this schedule again.
- **If your assigned testing calls for testing one certified product during each day that you are manufacturing certified product(s):**
    - After 6 months or 20 consecutive production runs of GFCO certified products (whichever is longer) with no positive gluten results in finished product, this may be reduced to one certified product during each week that you are manufacturing certified product(s).
    - After 1 year or 40 consecutive production runs of GFCO certified products (whichever is longer) with no positive gluten results in finished product, this may be reduced to one certified product during each month that you are manufacturing certified product(s).
    - After 18 months or 60 consecutive production runs of GFCO certified products (whichever is longer) with no positive gluten results in finished product, this may be reduced to one certified product during each calendar quarter that you are manufacturing certified product(s).
    - If at any point a finished product tests positive for gluten at >10 ppm, the plant must return to its most recently assigned testing requirement level and begin this schedule again.
- **If your assigned testing calls for testing one certified product during each week that you are manufacturing certified product(s):**
    - After 6 months or 20 consecutive production runs of GFCO certified products (whichever is longer) with no positive gluten results in finished product, this may be reduced to one certified product during each month that you are manufacturing certified product(s).
    - After 1 year or 40 consecutive production runs of GFCO certified products (whichever is longer) with no positive gluten results in finished product, this

may be reduced to one certified product during each calendar quarter that you are manufacturing certified product(s).
    - If at any point a finished product tests positive for gluten at >10 ppm, the plant must return to its most recently assigned testing requirement level and begin this schedule again.
- **If your assigned testing calls for testing one certified product during each month that you are manufacturing certified product(s):**
    - After 1 year or 40 consecutive production runs of GFCO certified products (whichever is longer) with no positive gluten results in finished product, this may be reduced to one certified product during each calendar quarter that you are manufacturing certified product(s).
    - If at any point a finished product tests positive for gluten at >10 ppm, 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.

A summary of this step-down schedule is provided in the table below:

	Contractual Finished Product Testing Requirement				
Step Down Timeline, greater of:	**3x/Lot**	**Per Lot**	**Per Day**	**Per Week**	**Per Month**
6 months or 20 consecutive GFCO runs	Per Lot	Per Day	Per Week	Per Month	Per Quarter
1 year or 40 consecutive GFCO runs	Per Day	Per Week	Per Month	Per Quarter	Per Quarter
18 months or 60 consecutive GFCO runs	Per Week	Per Month	Per Quarter	Per Quarter	Per Quarter
2 years or 80 consecutive GFCO runs	Per Month	Per Quarter	Per Quarter	Per Quarter	Per Quarter
30 months or 100 consecutive GFCO runs	Per Quarter	Per Quarter	Per Quarter	Per Quarter	Per Quarter

Visual Examination of Finished Products

In addition to the antibody-based testing discussed above, whole intact grains, seeds, beans, pulses and legumes that are sold as finished 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 visual examination, take a minimum of 20 samples from the lot, making sure to collect one sample from each container. Use an appropriate sampling tool that will allow 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 visual examination on these materials as incoming ingredients, you do not need to repeat it for the finished product.

Ingredients

All Plants who are registered with GFCO and who apply for certification will submit a list of the Products for certification, as well as all of the Ingredients used in those Products. These lists will be submitted directly to your chosen certification body, who will provide them to GFCO for review. 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:

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

<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 rare 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 finished 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 Plans

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

Risk Level 2: 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 as a Risk Level 3 ingredient prior to use in certified Product.

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 the a sampling plan validated by the Plant.

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.

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, 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 10.0 ppm, the entire ingredient lot/shipment cannot be used in certified Product.

Sampling for Ingredients with Large Particle Size or Relative Heterogeneity
Examples include grains, seeds, nuts, beans, 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 describe above 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) to take six representative samples per container – one near each corner of the container and two near the center. Reduce each sample to 100g using a Boerner divider or by coning and quartering, and grind them individually to the consistency of a flour. Individually test each of these 6 samples (not a composite) for gluten using a GFCO approved method, or the services of an ISO 17025 accredited laboratory. Keep the remainder of each of the six samples separate, and store them in the event that further testing is required. In the event of a confirmed positive (> 10 ppm) result from a rapid (lateral flow) test method, the remaining portion of each of the six samples taken must be tested individually using a quantitative method at an ISO 17025 accredited testing laboratory. If the gluten value of

any of these samples plus the laboratory's measurement uncertainty estimate is greater than 10.0 ppm, the entire ingredient lot cannot be used in certified Product.

Shared Equipment

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 on a regular basis.

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 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 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 be done by the Plant, using only 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 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 10 ppm, the GFCO threshold.

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

Notification of Out-of-Specification Product and Recalls

The registered Plant must notify GFCO at gfco.alerts@gluten.org immediately in the event of a confirmed positive gluten result (>10 ppm) in finished 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 result >10 ppm in a certified finished product, they should perform a second test.
2. If the result of that second test is also >10 ppm 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 it 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 3rd party lab results are > 10 ppm, 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 10 ppm, then we will determine the mean plus the laboratory's measurement uncertainty (or 2x the standard deviation, whichever is greater). If that value is less than 10 ppm the manufacturer can release the lot, but if that value is > 10 ppm 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 10 ppm, GFCO will review the method used to obtain the initial > 10 ppm results and make a determination regarding product release.

GFCO must also be notified, at the same address, 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 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 in 2020, with sign-ups from April 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, 2020, and a final report will be issued in January 2021. 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 free 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 73 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.

General Policies

Public Information

The GFCO Scheme maintains publicly available lists of approved Plants and certified Products, from all GFCO-approved certification bodies.

Any Plant that appears on a fully executed certification contract or certificate will appear on the GFCO Approved Plant list, unless the plant has indicated, at the time of registration, application or through written (email or mail) communication to GFCO, that they do not wish to appear on the public list. The information on the public Plant list will include:

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

All Products that appear on a current valid GFCO certificate will appear on the GFCO Certified Product list, unless the certification contract holder has indicated, on the Product & Ingredient list or through written (email or mail) communication to GFCO, that the Product should not appear on the public list. The information on the public Product list will include:

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

To request that Plant or Product information be removed from these public lists, contact GFCO via email at gfco.branding@gluten.org, or by mail to GFCO, 730C Commerce Center Drive, Sebastian, FL 32958.

Reduction, Probation, Suspension, Withdrawal or Termination of Certification

The certification body must immediately notify the GFCO Scheme when any of these statuses are assigned or removed. These statuses will be reflected on the GFCO registered plant list when they occur.

Each certification body must have written policies/procedures for reduction, suspension/probation, withdrawal or termination of certification that are available to their

clients. The certification body must make these documents and any related records available to GFCO on request.

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

Changes to the Certification

Clients must inform their certification body, and each certification body is responsible for immediately notifying the GFCO Scheme, in the event of any changes to a certification, including but not limited to:

- Contact information changes
- The addition, relocation or removal of Plants
- Changes in Company or Plant ownership
- Product or ingredient changes, removals or additions

Changing the Certification Body

Clients can change certification bodies at any time, provided they do not have any outstanding audit non-conformances, are not under threat of suspension, probation or withdrawal, and do not have any outstanding financial obligations.

Changing certification bodies will not affect the certification status of the Plant.

Certification Body Qualifications

All organizations offering certification to the GFCO Standard must be independently accredited to ISO 17065 - Requirements for Bodies Certifying Products, Processes, and Services.

Auditor Qualifications

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.

All new auditors, and every auditor once per year, will participate in 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 are also expected to complete any 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 the certification body'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:

- 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 their certification body immediately if they have been assigned to do so.
- The auditor should notify their certification body 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 auditors ability to conduct an impartial audit, or might be perceived as affecting the auditor's judgement.
- 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 certified companies or from their certification body.
- 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 into 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 in 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

Certification bodies must maintain records of auditor evaluations, and make these records available to GFCO upon request.

The GFCO Certification Standard

This section provides a detailed explanation of the GFCO Standard requirements, including a rationale or interpretation for each. This section also describes the types of evidence an auditor might look for in order to determine compliance with each requirement. 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.

Organizational Requirements

Brand Owner *by GFCO definition, a Brand Owner is the company that owns the brand name(s) of the Products submitted for certification. A Brand Owner may operate their own production facilities, or may have the Products manufactured in facilities that they do not own.*

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.

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 must state that they take responsibility for meeting the requirements of this standard.

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.

Evidence: A written statement in any document that is approved/signed by company management, such as in a Quality Manual or Operations Manual. 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 sold and 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.

Evidence: A written statement in any document that is approved/signed by company management, such as in a Quality Manual or Operations Manual. 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.

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 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 production of the certified product, and to observe any potential conflicts of interest.

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 or customer service related to the certified product(s) must have annual training on gluten and its risks. Records must be maintained that verify the effectiveness of this training.

Rationale: Awareness of gluten and its risks 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.

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 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 deputy must be appointed to act on this person's behalf in the event of their absence.

Rationale: GFCO requires a primary and back-up 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 back-up contact helps to ensure continuity of the certification program.

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 a complete list of 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 an accurate list of certified Products to provide to the manufacturing plant(s), to avoid mislabeling.

Evidence: A Product list 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, this evidence will not be reviewed during the facility audit, but should be available upon request.

8. If the Brand Owner is responsible for the product('s) formulation, then the Brand Owner must maintain a complete list 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.

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.

Evidence: An ingredient list 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, this evidence will not be reviewed during the facility audit, but should be available upon request.

9. The Brand Owner must maintain a list of commercial retailers of their certified products and provide the accrediting body with the list 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.

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 *by GFCO definition, a Plant is the location that performs some or all of the manufacturing and packaging steps for the Product(s) submitted for certification.*

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.

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 state that they take responsibility for meeting the applicable requirements of this standard.

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.

Evidence: A written statement in any document that is approved/signed by company management, such as in a Quality Manual or Operations Manual.

12. 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.

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

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."

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.

Evidence: A collection of written 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. But the policies and procedures must name and specifically address gluten and its risks.

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.

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.

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.

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.

16. The Plant must define and specify the activities of all key personnel involved in all steps in the creation of the certified product(s), including the organization and management structure of the company, it's connection to any co-producers/co-packers, it's 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 production of the certified product, and to observe any potential conflicts of interest.

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.

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. A deputy must be appointed to act on this person's behalf in the event of their absence.

Rationale: GFCO must have a designated contact person in all facilities that manufacture certified Product. Having a back-up contact helps to ensure continuity of the Gluten Program.

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.

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 certified Product is manufactured must be trained on the plant's Gluten Program.

Evidence: Training materials, training records, job descriptions, shift assignments or other means for indicating that the manager or supervisor for each shift where 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 appropriate personnel. All personnel operating under the Gluten Program must have annual training on their roles and responsibilities and in its proper maintenance. This includes all personnel involved in administration and manufacturing as well as those that interact with consumers. Records must be maintained that verify the effectiveness of this training.

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. Training should include an evaluation component, such as a quiz.

Evidence: Training materials, training records, evidence of the availability of relevant policies, procedures or work instructions; evidence that employee's understand their responsibilities within the Gluten Program.

22. All personnel operating under the Gluten Program must have annual training on gluten and its risks, and be encouraged to report instances of suspected contamination. Records must be maintained that verify the effectiveness of this training.

Rationale: The supervisor or manager on each production shift where certified Product is manufactured must be trained on the plant's Gluten Program.

Evidence: Training materials and training records for all personnel that interact with the public. Evidence that employees know the sources of gluten and the risks of gluten. 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 the fact that celiac disease is a serious health concern.

23. Plant management must provide evidence of commitment to the implementation and continual improvement of the Gluten Program through regular review of the program and its effectiveness.

Rationale: The Gluten Program must be regularly reviewed and improved as needed.

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 guaranty 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.

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.

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.

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 10 ppm limit.

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.

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.

27. The Plant must maintain a list or lists 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.

Evidence: A list of approved vendors and 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 foods.

Rationale: Purchasing documents are essential for traceability

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.

Rationale: Many suppliers sell both gluten-free and non-gluten-free versions of their raw materials. Purchasing document 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.

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 and inspecting incoming trucks and shipments, including verification that the correct materials are received.

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.

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 the proper labeling of 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.

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.

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.

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 an up-to-date list of all ingredients received in the plant that are used in gluten-free food production, including the name of each supplier and unique identifiers for each ingredient that agree with the ingredients' labeling.

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 identifier for purposes of traceability.

Evidence: An ingredient list maintained by the plant that matches the list on file with GFCO. Observation of unique labeling on each raw material used in gluten-free production. Evidence that employees can properly identify materials used in 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.

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.

Evidence: An ingredient list maintained by the plant that matches the list on file with GFCO.

35. The Gluten Program must include a requirement for the display or availability of instructions at all critical locations describing how best to avoid gluten contamination.

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.

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.

Evidence: Written cleaning schedules. Documentation that scheduled cleaning has occurred. Evidence that staff understand cleaning schedules.

37. The Gluten Program must include instructions for proper 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, and once validated the written instructions for the validated protocol(s)must be available to cleaning staff.

Evidence: Written cleaning protocols with evidence that their effectiveness has been validated. Observation that these protocols are 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 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.

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.

39. The Gluten Program must include a written analysis of the production process, including identification of all points at which gluten contamination or mislabeling might occur.

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.

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.

Rationale: Accurate, detailed batch records are necessary for traceability of both Products and raw materials.

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 an up-to-date list of certified products manufactured in the plant, including unique identifiers for each product that agree with the products' labeling.

Rationale: The plant must keep an accurate list of certified Products, to avoid mislabeling. The Product names on this list must match the Product names on the certificate and the Product packaging.

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.

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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.

Evidence: A Product list maintained by the plant that matches the list on file with GFCO.

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.

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 shall include the product lot number, date of production, size of production lot, 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.

Rationale: Production batch records must contain sufficient information to allow traceability and investigation of contamination incidents, and must be kept for as long the Product might be available for sale. Completed batch records should be reviewed for accuracy and completeness following each production run.

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 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.

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 and clearly communicated and available to employees.

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 food handling procedures that will eliminate cross-contamination.

Rationale: Gluten contamination can be introduced by persons entering the plant, so everyone who has access to the plant should observe hygiene requirements.

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-contamination.

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.

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 regular review of possible sources of carryover or cross-contamination between product lines in those plants producing both gluten-containing and gluten-free products.

Rationale: In mixed-use facilities, any changes in production schedules, staff, equipment or processes can affect the gluten status of 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.

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 affect on the Gluten Program.

50. The Gluten Program must include procedures for assuring that the correct packaging and labeling is used on finished products. If packaging occurs separately from production, the Program must include procedures for sequencing packaging activities and cleaning packaging facilities and equipment between lots in order to eliminate carryover or cross-contamination.

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.

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 gluten-free products.

Rationale: The plant must ensure that their warehouse and the trucks that distribute their finished products are not a source of gluten contamination.

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 shipping area is free of gluten contamination.

52. The Gluten Program must include procedures for handling rework materials, including documentation allowing traceability of all rework products, when applicable.

Rationale: In plants that use rework, procedures must be in place to ensure that rework is not a potential source of gluten contamination, and that all rework can be traced.

Evidence: Written procedure for handling and tracking rework. Observation that rework is tracked on batch records.

53. The Gluten Program must include procedures for sequestering and 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.

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 procedures and acceptable materials for using purge material between production runs, and for the use or disposal of purge materials, when applicable.

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.

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.

55. The Gluten Program must include procedures for controlling and monitoring airborne dust in situations where this might present a risk.

Rationale: Gluten-containing airborne dust can present a risk to gluten-free production. If the plant generates gluten-containing dust there must be processes in place to prevent it from contaminating gluten-free product.

Evidence: 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 Gluten Program must include procedures for validating the effectiveness of the plan.

Rationale: Plants producing certified product must demonstrate that their Gluten Plan is effective in mitigating risks to gluten-free production.

Evidence: Verification testing data on finished products. Analysis of contamination incidents or consumer complaints.

57. The Gluten Program must include a complete two-way traceability scheme for all ingredients and products.

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.

Evidence: Batch records that include specific ingredient names/lot numbers; outgoing shipping records for all products.

58. The Gluten Program must contain a general Corrective Action procedure for any instances of contamination or suspected contamination, 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.

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 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.

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 raw materials that are found to be contaminated.

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.

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 contamination of facilities, equipment or work tools.

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.

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 contaminated product that has not yet left the plant.

Rationale: Plants need to have clear instructions for handling finished product that is found to contain gluten at a level greater than 10 ppm, in order to avoid the accidental release of this product for sale.

Evidence: A written process for dealing with finished product that contains greater than 10 ppm gluten that 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 or specific procedures for handling instances of mislabeling or mispackaging of products.

Rationale: Plants need to have clear instructions for handling finished product that is mislabeled or mispackaged in order to avoid the accidental release of this product for sale.

Evidence: A written process for dealing with 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 contamination discovered in product sent to customers or on the open market (recall plan).

Rationale: The plant must have a process for handling recalls and withdrawals, and verify the effectiveness of this process.

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.

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 the certification body.

Rationale: Only properly validated gluten test methods can be used for validation and verification activities.

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.

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 shall 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.

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 shall undergo a matrix validation for a chosen method using a validation protocol approved by the certification body. 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.

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 the certifying body and written in the certification contract or any subsequent addenda.

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.

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 the certifying body each quarter.

Rationale: The plant or brand owner is contractually obligated to submit their testing results to GFCO each calendar quarter for review.

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 who 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.

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 the certifying body (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.

Evidence: Documentation of successful participation in a proficiency testing scheme for gluten within the past 4 years.

73. Any unexpected positive testing results (above the acceptable limit of 10 ppm) from external or internal testing will require a Corrective Action.

Rationale: Any positive gluten test results in certified finished product must be investigated through the plant's corrective action process, since these results will always be unexpected.

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 Corrective Action.

Rationale: If the plant does not obtain the expected results during proficiency testing, they will need to examine the source of the error.

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.

75. If the product being certified is not commercially available, the Plant must allow access to staff of the certifying body to collect surveillance samples during production.

Rationale: Finished product surveillance is an important part of GFCO certification, so plants must make product available for testing by GFCO.

Evidence: Collection of test samples by auditors or GFCO staff.

76. The Plant must show evidence of continual improvement of their gluten program through regular review with management.

Rationale: Plant management must be committed to continually improving the Gluten Program. This can be achieved through review of the program's policies and procedures, or other meetings or reviews of the program.

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 regular mock recalls and follow up on the results of these exercises with any necessary corrective actions.

Rationale: In the absence of any actual product recalls, the plant must perform mock recalls to validate the effectiveness of their recall plan.

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 of their systems and program and if these audits demonstrate any deficiencies in their policies, procedures or programs, initiate appropriate corrective actions.

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.

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.

79. The Plant and Brand Owner must only use the GF symbol on the products listed in the certification contract, and in the manner defined in the certification contract.

Rationale: The GFCO certification mark can only appear on products that are reviewed and approved by GFCO, and that appear on the certificate.

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 Guide.

80. The use and format of the GF 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.

Evidence: Documentation of GFCO approval for all packaging proofs, advertising, marketing materials, etc. bearing the GFCO logo.

Revision History:

December 30, 2019 (rev 2020)
Page 1: Revision changed from 2019 to 2020
Page 8: SGS removed from list of approved GFCO certification bodies
Page 22: first paragraph changed from:

> GFCO offers a PT round each year, with sign-ups beginning September 1st at www.gluten.org/proficiency-registration. 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 free check samples for the users of their test kits. All of these programs are suitable for meeting the GFCO Standard requirement.
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> to:
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> GFCO will offer a PT round in 2020, with sign-ups from April 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, 2020, and a final report will be issued in January 2021. There are other organizations that offer gluten PT rounds commercially — LGC Standards in the United States (www.lgcstandards.com), FAPAS (www.fapas.com) in the United Kingdom, and Bipea (www.bipea.org) in Spain are three examples, and their programs are accredited under ISO 17043. Additionally, some test kit manufacturers offer free check samples for the users of their test kits. All of these programs are suitable for meeting the GFCO Standard requirement.