STANDARDS

Grain-Free® Standards

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SPEARHEAD

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Statement of Purpose

A recent Nielsen survey found that nearly two out of three global consumers exclude specific ingredients from their diets, and one of the most excluded food ingredients are grains. Another Nielsen report found that over a 52-week period, sales of products that included a "Grain-free" label went up more than 75 percent.

Grain-free seems to be at the crossroads of the Paleo Diet and Gluten-Free food trends. And while some argue that going grain-free is too limited and unnecessary for most dieters, increasing evidence suggests that a Grain-free diet may be beneficial for many people with digestive disorders and metabolic syndromes.

In tandem with the increasing need for grain-free products, grain-free claims needed to be standardized and implemented. In the development of the Grain-Free Certified Program, The Paleo Foundation designed a three-round audit system that includes stringent and accredited lab-testing to ensure that certified products have met both grain-free and gluten-free requirements. The Standards for this program are outlined herein.

Best,

Karen Pendergrass
Paleo Foundation
Standards Team

The 4 Major Factors That Influence Diet Tolerability

Availability: Product Offerings, Location and Limitation of Products

Affordability: Socio-Economic Limitations, Distribution Limitations

Palatability: Product Variations, Ideological Acceptance

Convenience: Cultural Acceptance, Ease of Identification

Grain-Free Standards & Development Team

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Scope of Certification

The Paleo Foundation certifies Products in the categories of Food, Beverages, Supplements, and Personal Care. Grain-Free certification is specific to a product or products made at a single manufacturing plant or number of plants. For Grain-Free Certification, each plant and product must comply with the Grain-Free Certification requirements to bear the Grain-Free Certification label. The Paleo Foundation confirms this compliance through a 3-Round Auditing process.

The Paleo Foundation requires cooperation from all parties involved in producing the products applying for Grain-Free Certification. Applicants must disclose all plants engaged in the production of Grain-Free Certified products, as all parties must adhere to an agreed-upon set of policies and procedures outlined by The Paleo Foundation that are determined by a Relative Risk Assessment.

Because compliance of all parties is necessary for the Grain-Free Certification, legal entities allowed to apply for certification include the manufacturing facility that produces the products, or the brand owner. Applicants must ensure that their co-manufacturers are able to meet all of the Co-manufacturers Requirements outlined herein before permissions for Grain-Free certification will be provided.

Auditing Procedures

Round 1: Once the application and payment for certification and lab tests have been received, The Paleo Foundation will make a preliminary Round 1 audit to determine the eligibility of the products for the Grain-Free program. If the products do not meet the eligibility requirements for ingredients, The Paleo Foundation may assist in ingredient formulations to achieve eligibility, or a refund in full for the licensing and lab tests will be issued.

Round 2: The Paleo Foundation will review the following information:

- Policies and Procedures relating to product production
- Organizational chart, job descriptions
- Vendor statements on grains or gluten (if available)
- Hazard analysis (if available)

Round 3: The products will be sent to an ISO accredited laboratory for final review, where they will be tested for gluten and gliadin competitive assay to ensure Grain-Free Standards Compliance. Brands will receive a copy of the lab results, and the Auditing Team will designate brands to a Relative Risk Category that will determine the level of scrutiny by the Paleo Foundation for the Grain Free Certification program.

Ongoing Auditing and Surveillance will occur throughout the agreement period based on a category determined by the Relative Risk Assessment outlined herein.

Relative Risk Assessment

The company's risk level for grain and gluten contamination will be determined by The Paleo Foundation. The level of scrutiny for The Paleo Foundation's Grain-Free Certification program is relative and will depend on a number factors:

Relative Risk A: This category is applied for products with the lowest risk of grain or gluten contamination, such as fats and oils.

Relative Risk B: This category is applied for products that have low risk of grain or gluten contamination. Ingredients in this category include items that may share some part of the supply chain with grains or have had rare incidents of cross-contamination. Products in this category may also include moderate-risk ingredients that have adequate testing documentation for each lot.

Relative Risk C: This category is applied for product(s) that contain ingredients that have a moderate risk for cross-contamination due to commonly shared supply chain or production with grains. Products in this category may also include high-risk ingredients that have adequate testing documentation for each lot.

Relative Risk D: This category is applied for product(s) that contains ingredients that have a high risk for gluten cross-contamination because they share one or more steps of the supply chain with grains, or have had more frequent incidents of cross-contamination.

Grain-Free Standards

Program Standards and Specifications

1. Grain-Free Certified ™ Label

The Grain-Free Certified Requirements for Grain-Free, Legume-Free, Dairy-Free, Artificial Coloring, Artificial Preservatives, Artificial Sweeteners and Artificial Flavor Enhancers-Free Products are outlined herein. These standards apply to all products certified by The Paleo Foundation for the Grain-Free Certified Program. Only certified Products following these standards are explicitly given the rights to use Grain-Free Certified logos, trademarks, certification marks, or other design marks hereinafter referred to as "Grain-Free Certified label".

1.1 Applicability

The Grain-Free Certified label was developed and trademarked by the The Paleo Foundation to identify food products that meet the standards of a Grain-Free diet. The Grain-Free Certified label is a certification mark, and its use is only permitted by those who have entered into a contractual agreement with The Paleo Foundation. The Grain-Free Certified label was designed to establish an easily identifiable mark indicating that a product does not contain grains, or gluten.

1.2 Guidelines

1.2.1
The Grain-Free Certified label is allowed to be used on packaging, promotional materials, point of purchase materials, websites, sales literature, banners, company stationery, and other advertising materials. Use of the Grain-Free Certified label must comply with the guidelines as outlined in this document. If a company wishes to present the logos in a manner other than as described in Statement of Use Guidelines, The Paleo Foundation must approve the request and give permission in writing to the Producer.

1.2.2
Producers may display the Grain-Free Certified ™ label only on products that have been certified by The Paleo Foundation.

1.2.3
Producers must have a contractual agreement with The Paleo Foundation to use the Grain-Free Certified label.

1.2.4
Producers may only use the trademark on company stationery if the entire product line has been audited and Grain-Free Certified.

1.2.5
If the entire product line has been audited and Grain-Free Certified, producers may display the label on their entire website.

1.2.6
If the entire product line was not certified, the Grain-Free Certified label may appear on a page containing the audited and Grain-Free Certified products only.

1.2.7
Products that have not been audited and Grain-Free Certified are not permitted to appear on the same page as the Grain-Free Certified label, as this could mislead consumers.

1.3 Use of the Grain-Free Certified ™ Label

1.3.1
To complete the application process, the applicant must sign an affidavit stating that all answers and statements provided in their application were true to the best of their knowledge.

1.3.2
Use of the Grain-Free Certified™ label is only permitted after audit and certification of the applicant's products by The Paleo Foundation.

1.3.3
The Paleo Foundation retains the right to inspect the producer's products to verify that all requirements are met.

1.3.4
Use of the label for any product that does not meet each of the Grain-Free Certified requirements, that has not been audited, or that has not been given explicit permission, is strictly prohibited.

1.3.5
Misuse of the Grain-Free Certified Label will result in immediate suspension of the agreement and/or prosecution.

1.3.7
The Grain-Free Certified label must be :

① Upright
② Complete
③ Clearly Visible

2. Grain-Free

2.0.1
All Grain-Free Certified Products must not contain grains or pseudograins and be grain-free to be eligible for use of the Grain-Free Certified label. There are no exceptions to this rule. Disallowed grains and pseudograins include, but are not limited to:

Name	Latin Name	Type
Amaranth	*Amaranthus cruentus*	Pseudograin
Barley	*Hordeum vulgare*	Grain
Buckwheat	*Fagopyrum esculentum*	Pseudograin
Bulgur	*Triticum ssp.*	Grain
Corn	*Zea mays mays*	Grain
Farro	*Triticum spelta, Triticum dicoccum, Triticum monococcum*	Grain
Farro / Einkorn	*Triticum monococcum L*	Grain
Farro / Emmer	*Triticum turgidum dicoccum*	Grain
Farro / Spelt	*Triticum aestivum spelta*	Grain
Millet	*Panicum miliaceum, Pennisetum Glaucum, Setaria italica, eleusine coracana, digitaria exilis*	Pseudograin
Freekeh / Farik	*Triticum turgidum var. durum*	Grain
Durum Wheat	*Triticum durum or Triticum turgidum subsp. durum*	Grain

2.0.1 Continued

Khorasan Wheat	*Triticum turgidum turanicum*	Grain
Oats	*Avena sativa*	Grain
Quinoa	*Chenopodium quinoa*	Pseudograin
Kañiwa	*Chenopodium pallidicaule*	Pseudograin
Rice	*Oryza sativa, Oryza glaberrima*	Grain
Rye	*Secale cereale*	Grain
Sorghum	*Sorghum spp.*	Grain
Teff	*Eragrostis tef*	Grain
Triticale	*x Triticosecale rimpaui*	Grain
Wheat	*Triticum aestivum*	Grain
Wild Rice	*Zizania spp.*	Grain

3. Gluten and Gliadin-Competitive Free

3.0.1

The FDA defines gluten-free as an end product containing less than 20 parts per million of gluten. However, the Paleo Foundation requires that products test at less than 10ppm of gluten and gliadin competitives for Grain Free Certification.

™

Grain-Free Certified Standards for products,

Licensing Agreements

A preliminary copy of the Licensing Agreement template may be requested at the time of application. The Licensing Agreement also defines which parties will be held responsible for meeting the program requirements and ongoing testing determined by the Relative Risk Assessment.

If the owner operates the plant, the owner bears sole responsibility for upholding the Grain-Free Certification Standards and surveillances outlined herein. If the brand owner does not own the manufacturing facility or does not oversee the production of his or her products, then the brand owner and facility must both accept responsibility for upholding the Grain-Free Certification Standards.

The Licensing Agreement provides the applicant with the requirements for the use of the Grain-Free logos. Exhibits of the agreement will include:

- A current copy of the Grain-Free Certification Standards
- A signed affidavit stating an agreement to comply with Manufacturing Requirements as determined by an assigned Relative Risk Assessment
- Lab reports indicating that the requirements of the program have been met

Non-Conformance

Non-conformance issues are the greatest issue faced by brands during the certification process. However, there are distinct differences in approach to the common non-conformance issues prior to certification and the common non-conformance issues after a product has been Grain-Free Certified by the Paleo Foundation.

Non-conformance issues prior to certification: Once documentation is reviewed, and products have undergone the final audit, determination of Grain-Free Certification eligibility will be reviewed by the Auditing Team. If non-conformances are found, corrective action procedures must be undertaken to finalize Grain-Free Certification and agreements.

Common non-conformance issues prior to the initial certification include:

- An ingredient or its sub-ingredients contains a disallowed grain or grain-derived element.
- The co-manufacturer is not willing to agree to the terms of the Manufacturing Requirements determined by their assigned Relative Risk Assessment.
- An ingredient supplier refuses to offer documentation during the first round of audits.

Disallowed Ingredients*:* In the event that an ingredient or sub-ingredients contains a disallowed grain or grain-derived element, The Paleo Foundation will assist in finding appropriate alternatives to the ingredient or assist in vetting new suppliers.

Uncooperative Manufacturers*:* In the event that a co-manufacturer is not willing to agree to the terms of the Manufacturing Requirements, an appeal may be made to amend the requirements, or a new co-manufacturer may be necessary to proceed with Grain-Free Certification.

Uncooperative Ingredient Suppliers*:* In the event that an ingredient supplier refuses to offer documentation to The Paleo Foundation, the applicant may approve moving forward with the round 3 lab tests. However, this becomes a risky choice as lab tests are non-refundable.

Non-conformance issues after certification: Issues that may arise post-certification have more serious ramifications and may result in a withdrawal of products from the Grain-Free Certified program. Issues that arise after certification often include:

-Packaging non-conformance
-Non-conformance with a new ingredient supplier
-Non-conformance or low cooperation with new plant
-Positive swab tests

Packaging Non-conformance: The Grain-Free logo may only appear on products that have been approved by The Paleo Foundation. However, if the label was printed erroneously on a package, the brand will be permitted a feasible time period to remove the logo from the product packaging and must announce the mistake on their website as a temporary means of remediation.

Non-conformance with a new ingredient supplier: If a new ingredient supplier refuses to offer necessary documentation to the Auditing Team, the product may be withdrawn from the Grain-Free Certification program.

Non-conformance with a new manufacturing facility: If a new manufacturer refuses to agree to the terms of the Relative Risk Assessment Category Requirements assigned to the products, products produced at the facility will not be permitted authorization to use the Grain-Free logo.

Positive swab tests: Either the brand or manufacturing facility must notify The Paleo Foundation immediately if a positive gluten result (>10 ppm) in a finished product has occurred. The manufacturer must detail their findings from the root cause analysis and provide them to The Paleo Foundation. The Paleo Foundation may issue a new Relative Risk Assessment Category or may not allow the products to feature the Grain-Free logos based on findings.

Appeals

While failure to meet the non-conformance requirements may result in the denial or withdrawal of products or manufacturing plants in the Grain-Free Certification program, appeals are permissible.

Brands may appeal certain Auditing Team decisions by contacting their Auditing Team Representative assigned to their case, and any Paleo Foundation representative may appeal on behalf of the brand or applicant. The following appeals are permissible:

- The decision to deny certification
- The decision to withdraw a product from the program
- The category assigned from the Relative Risk Assessment

The decision to grant or deny certification*:* Licensees or Manufacturers may submit arguments with supporting documentation to appeal The Paleo Foundation's decision to deny certification to a specific product.

The decision to withdraw a product from certification*:* Because of the serious nature of withdrawal of a product from the Grain-Free program, brands and manufacturers may appeal decisions by providing up to 4 new action plans to satisfy the requirements of the Grain-Free Program in writing that must be approved by a Paleo Foundation representative to maintain good standing.

Category Assignment*:* Brands and Manufacturing Facilities may appeal their assigned category by providing new documentation that supports the request. An internal review board consisting of Auditing Team and Standards Team members will meet to determine whether to accept the appeal, and the decision will be given in writing.

Relative Risk Assessment

The Paleo Foundation will determine the brand's Relative Risk category based on their prospective level of risk for grain and gluten contamination. Relative Risk is categorized by a number of factors and will determine the level of scrutiny by The Paleo Foundation for the Grain Free Certification program. The relative risk category will be determined at the end of the auditing process and assessed as follows:

Relative Risk A: The product contains ingredients with no perceived risk for grain contamination. Ingredients in this category include fats, oils, and other additives that do not contain protein.

Relative Risk B: The product contains ingredients that have been determined to be low risk for use in grain-free foods for gluten contamination. Ingredients in this category include items that may share some part of the supply chain with grains or have had rare incidents of cross-contamination. Ingredients in this category may also include moderate-risk items that have adequate supplier documentation.

Relative Risk C: The product contains ingredients that have a moderate risk for cross-contamination because they commonly share some part of the supply chain with grains. Ingredients in this category may also include high-risk items that have appropriate vendor testing documentation for each lot.

Relative Risk D: The product contains ingredients that have a high risk for grain cross-contamination because they share one or more steps of the supply chain with grains.

The gluten-free status of an ingredient, proof of ongoing lot-specific gluten testing done by the ingredient supplier, or a copy of an ingredient supplier's lab tests indicating gluten and/or grain—free status can impact the Relative Risk Assessment and should be emailed to The Paleo Foundation at the time of application.

Manufacturing Requirements

Manufacturing Requirements will be determined by the category assigned during the Relative Risk Assessment. The manufacturers must be responsible for upholding the requirements of the Grain-Free Certification program and ongoing on-site surveillance. Co-manufacturers are obliged to sign an affidavit stating that all requirements outlined in the assigned Relative Risk Assessment Category will be met.

The requirements of each category are outlined herein.

Category B

Category B Manufacturing Requirements

1. Category B Manufacturing Requirements

Certification is a process that affects all levels of policies and procedures for a product manufacturer. As manufacturers are most responsible for compliance and on-site surveillance, an affirmation by the manufacturing facility's management is required for the Grain-Free Certification program. Category B Manufacturing Requirements are outlined herein.

1.1 Necessary Authorization

1.1.1

Food manufacturers must have the necessary permits required to manufacture and sell food, granted by their state or equivalent level of government.

1.1.2

Manufacturing Facilities must meet all applicable local, regional, and/or national requirements for the production and packaging of the product(s).

1.2 Manufacturing Procedures

1.2.1
The Manufacturing Facility must have written procedures in place that specifically address the control of cross-contamination.

1.2.2
The Manufacturing Facility must have written documentation that defines and specifies 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, its connection to any co-producers/co-packers, its place in any larger organization, and the relationship between quality management and production operations such as an organizational chart, or other written description of the management structure of the manufacturing facility.

1.2.3
The supervising personnel involved in the production of products must be aware of the requirements of the Grain-Free Certification program.

1.2.4
The Manufacturing Facility must have personnel with the training and authority to identify potential non-compliance of the Grain Free Certification Program and to initiate action to prevent, correct, or minimize non-compliances.

1.2.5
The Manufacturing Facility must perform production activities in such a way that satisfies the requirements of the Grain-Free Certification program.

1.2.6
The Manufacturing Facility must have a key person or position to act as the primary contact with The Paleo Foundation for all matters related to Grain-Free certification.

1.2.7
The Manufacturing Facility must have written proper cleaning protocols between Grain-Free Certified products and other products on shared machinery.

1.2.8
The Manufacturing Facility must perform a gluten swab test with an approved kit prior to the production of Grain-Free Certified products.

1.2.9
The Manufacturing Facility must have an HACCP plan or other analysis that identifies high-risk points in their production process for contamination or misidentification.

1.3 Record-Keeping

1.3.1
The Manufacturing Facility must maintain records of purchasing for all materials used in the production of gluten-free foods for up to one year.

1.3.2
The Manufacturing Facility must maintain records of purchasing for all materials used in the production of gluten-free foods for up to one year.

1.3.3
The Manufacturing Facility must ensure that each raw material has a unique identifier for purposes of traceability.

1.3.4
The Manufacturing Facility must maintain records of performed cleanings for up to two years.

1.3.5
The Manufacturing Facility must maintain batch records of products, including date of production, product lot number, and raw materials for two years to allow sufficient traceability.

1.3.6
Records of consumer complaints about suspected contamination must be kept for two years.

2. Production Requirements

2.0.1
If the Manufacturing Facility is responsible for the formulation of the certified product(s), any updates or alterations to the ingredients, or ingredient suppliers, or product formulations must be approved by The Paleo Foundation.

2.0.2
Regular cleaning schedules must be performed, as they are essential for maintaining a production environment in concert with the Grain-Free Certification program.

2.0.3
The Grain-Free logo may only be applied to Grain-Free Certified products that appear on the Permissions Letter.

3. Contamination Requirements

3.0.1
The Manufacturing Facility must have a written procedure for corrective actions to be taken in the event of contamination following a Root Cause Analysis and must have methods of determining the effectiveness of the procedure.

3.0.2
The Manufacturing Facility must notify The Paleo Foundation in the event of a confirmed positive contamination result from a post-production swab.

3.0.3
The Manufacturing Facility must have a written recall plan or a mock recall that was successfully completed within the past year.

B

As a legal representative of _____, a _____ Corporation, I agree to uphold the terms in the Category B Manufacturing Requirements for Grain-Free Certification. I also agree to supply Paleo Certified Inc. dba The Paleo Foundation with documentation that they may request, relative only to maintaining the integrity of the Grain-Free Certification program.

I understand that although The Paleo Foundation does not require on-site audits of manufacturing facilities for this category, The Paleo Foundation reserves the right to change a manufacturing facility's Relative Risk Assessment Category in the event of a positive test for gluten and/or gliadin contamination.

_____

Signature

_____

Name

_____

Title

_____

Date

Category C

Category C Manufacturing Requirements

1. Category C Manufacturing Requirements

Certification is a process that affects all levels of policies and procedures for a product manufacturer. As manufacturers are most responsible for compliance and on-site surveillance, an affirmation by the manufacturing facility's management is required for the Grain-Free Certification program. Category B Manufacturing Requirements are outlined herein.

1.1 Necessary Authorization

1.1.1

Food manufacturers must have the necessary permits required to manufacture and sell food, granted by their state or equivalent level of government.

1.1.2

Manufacturing Facilities must meet all applicable local, regional, and/or national requirements for the production and packaging of the product(s).

1.2 Manufacturing Procedures

1.2.1
The Manufacturing Facility must have written procedures in place that specifically address the control of cross-contamination.

1.2.2
The Manufacturing Facility must have written documentation that defines and specifies 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, its connection to any co-producers/co-packers, its place in any larger organization, and the relationship between quality management and production operations such as an organizational chart, or other written description of the management structure of the manufacturing facility.

1.2.3
The supervising personnel involved in the production of products must be aware of the requirements of the Grain-Free Certification program.

1.2.4
The Manufacturing Facility must have personnel with the training and authority to identify potential non-compliance of the Grain Free Certification Program and to initiate action to prevent, correct, or minimize non-compliances.

1.2.5
The Manufacturing Facility must perform production activities in such a way that satisfies the requirements of the Grain-Free Certification program.

1.2.6
The Manufacturing Facility must have a key person or position to act as the primary contact with The Paleo Foundation for all matters related to Grain-Free certification.

1.2.7
The Manufacturing Facility must have written proper cleaning protocols between Grain-Free Certified products and other products on shared machinery.

1.2.8
The Manufacturing Facility must perform a gluten swab test with an approved kit prior to the production of Grain-Free Certified products.

1.2.9
The Manufacturing Facility must have an HACCP plan or other analysis that identifies high-risk points in their production process for contamination or misidentification.

1.3 Record-Keeping

1.3.1
The Manufacturing Facility must maintain records of purchasing for all materials used in the production of gluten-free foods for up to one year.

1.3.2
The Manufacturing Facility must maintain records of purchasing for all materials used in the production of gluten-free foods for up to one year.

1.3.3
The Manufacturing Facility must ensure that each raw material has a unique identifier for purposes of traceability.

1.3.4
The Manufacturing Facility must maintain records of performed cleanings for up to two years.

1.3.5
The Manufacturing Facility must maintain batch records of products, including date of production, product lot number, and raw materials for two years to allow sufficient traceability.

1.3.6
Records of consumer complaints about suspected contamination must be kept for two years.

2. Production Requirements

2.0.1
If the Manufacturing Facility is responsible for the formulation of the certified product(s), any updates or alterations to the ingredients, or ingredient suppliers, or product formulations must be approved by The Paleo Foundation.

2.0.2
Regular cleaning schedules must be performed, as they are essential for maintaining a production environment in concert with the Grain-Free Certification program.

2.0.3
The Grain-Free logo may only be applied to Grain-Free Certified products that appear on the Permissions Letter.

3. Contamination Requirements

3.0.1
The Manufacturing Facility must have a written procedure for corrective actions to be taken in the event of contamination following a Root Cause Analysis and must have methods of determining the effectiveness of the procedure.

3.0.2
The Manufacturing Facility must demonstrate beyond a reasonable doubt that their plan is effective in mitigating risks of contamination in the production of Grain-Free Certified products.

3.0.3
The Manufacturing Facility must notify The Paleo Foundation in the event of a confirmed positive contamination result from a post-production swab.

3.0.4
The Manufacturing Facility must employ a gluten swab test on the line prior to production and after production of the Grain-Free Certified product.

3.0.5
The Manufacturing Facility must have a written recall plan or a mock recall that was successfully completed within the past year.

3.0.6
The Manufacturing Facility must perform an internal audit in the event of a positive swab test. Internal audits must address all relevant requirements of the Grain-Free Certification program. Any non-conformances must be addressed if found.

C

As a legal representative of _____, a _____ Corporation, I agree to uphold the terms in the Category C Manufacturing Requirements for Grain-Free Certification. I also agree to supply Paleo Certified Inc. dba The Paleo Foundation with documentation that they may request, relative only to maintaining the integrity of the Grain-Free Certification program.

I understand that although The Paleo Foundation does not require on-site audits of manufacturing facilities for this category, The Paleo Foundation reserves the right to change a manufacturing facility's Relative Risk Assessment Category in the event of a positive test for gluten contamination.

_____

Signature

_____

Name

_____

Title

_____

Date

LAB-TESTED GRAIN FREE CERTIFIED™

Category D

Category D Manufacturing Requirements

1. Category C Manufacturing Requirements

Certification is a process that affects all levels of policies and procedures for a product manufacturer. As manufacturers are most responsible for compliance and on-site surveillance, an affirmation by the manufacturing facility's management is required for the Grain-Free Certification program. Category B Manufacturing Requirements are outlined herein.

1.1 Necessary Authorization

1.1.1

Food manufacturers must have the necessary permits required to manufacture and sell food, granted by their state or equivalent level of government.

1.1.2

Manufacturing Facilities must meet all applicable local, regional, and/or national requirements for the production and packaging of the product(s).

1.2 Manufacturing Procedures

1.2.1
The Manufacturing Facility must have written procedures in place that specifically address the control of cross-contamination.

1.2.2
The Manufacturing Facility must have written documentation that defines and specifies 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, its connection to any co-producers/co-packers, its place in any larger organization, and the relationship between quality management and production operations such as an organizational chart, or other written description of the management structure of the manufacturing facility.

1.2.3
The supervising personnel involved in the production of products must be aware of the requirements of the Grain-Free Certification program.

1.2.4
The Manufacturing Facility must have personnel with the training and authority to identify potential non-compliance of the Grain Free Certification Program and to initiate action to prevent, correct, or minimize non-compliances.

1.2.5
The Manufacturing Facility must perform production activities in such a way that satisfies the requirements of the Grain-Free Certification program.

1.2.6
The Manufacturing Facility must have a key person or position to act as the primary contact with The Paleo Foundation for all matters related to Grain-Free certification.

1.2.7
The Manufacturing Facility must have written proper cleaning protocols between Grain-Free Certified products and other products on shared machinery.

1.2.8
The Manufacturing Facility must perform a gluten swab test with an approved kit prior to the production of Grain-Free Certified products.

1.2.9
The Manufacturing Facility must have an HACCP plan or other analysis that identifies high-risk points in their production process for contamination or misidentification.

1.3 Record-Keeping

1.3.1
The Manufacturing Facility must maintain records of purchasing for all materials used in the production of gluten-free foods for up to one year.

1.3.2
The Manufacturing Facility must maintain records of purchasing for all materials used in the production of gluten-free foods for up to one year.

1.3.3
The Manufacturing Facility must ensure that each raw material has a unique identifier for purposes of traceability.

1.3.4
The Manufacturing Facility must maintain records of performed cleanings for up to two years.

1.3.5
The Manufacturing Facility must maintain batch records of products, including date of production, product lot number, and raw materials for two years to allow sufficient traceability.

1.3.6
Records of consumer complaints about suspected contamination must be kept for two years.

2. Production Requirements

2.0.1
If the Manufacturing Facility is responsible for the formulation of the certified product(s), any updates or alterations to the ingredients, or ingredient suppliers, or product formulations must be approved by The Paleo Foundation.

2.0.2
Regular cleaning schedules must be performed, as they are essential for maintaining a production environment in concert with the Grain-Free Certification program.

2.0.3
The Grain-Free logo may only be applied to Grain-Free Certified products that appear on the Permissions Letter.

3. Contamination Requirements

3.0.1
The Manufacturing Facility must have a written procedure for corrective actions to be taken in the event of contamination following a Root Cause Analysis and must have methods of determining the effectiveness of the procedure.

3.0.2
The Manufacturing Facility must demonstrate beyond a reasonable doubt that their plan is effective in mitigating risks of contamination in the production of Grain-Free Certified products.

3.0.3
The Manufacturing Facility must notify The Paleo Foundation in the event of a confirmed positive gluten contamination result from a post-production swab.

3.0.4
The Manufacturing Facility must employ a gluten swab test on the line prior to production and after production of the Grain-Free Certified product.

3.0.5
The Manufacturing Facility must have a written recall plan or a mock recall that was successfully completed within the past year.

3.0.6
The Manufacturing Facility must perform an internal audit in the event of a positive swab test. Internal audits must address all relevant requirements of the Grain-Free Certification program. Any non-conformances must be addressed if found.

3.0.7
After non-conformance has been addressed, the Manufacturing Facility or Brand Owner must test raw materials, equipment, and finished products. All test results must be submitted once per quarter for up to one year and must show continued compliance.

D

As a legal representative of _____, a _____ Corporation, I agree to uphold the terms in the Category C Manufacturing Requirements for Grain-Free Certification. I also agree to supply Paleo Certified Inc. dba The Paleo Foundation with documentation that they may request, relative only to maintaining the integrity of the Grain-Free Certification program.

I understand that although The Paleo Foundation does not require on-site audits of manufacturing facilities for this category, The Paleo Foundation reserves the right to change a manufacturing facility's Relative Risk Assessment Category in the event of a positive test for gluten contamination.

_____

Signature

_____

Name

_____

Title

_____

Date

Frequently Asked Questions [1]

This a dedicated Grain-Free Facility required for a product to be Grain-Free Certified? No. While a dedicated grain-free facility does reduce the risk of grain contamination, it is not necessary for a product to be produced in a grain-free facility.

Do Grain-Free Certified products need to be produced on a dedicated line? No. Proper and thorough cleaning techniques can result in a product that is safe and grain-free, even if a shared line is used.

What are the testing requirements for the Grain-Free program? The Paleo Foundation requires that all finished products contain less than 10ppm of gluten, gliadin, and gliadin competitive.

Does The Paleo Foundation audit my labels?
The Paleo Foundation may review labels to ensure that proper usage is met. However, The Paleo Foundation is not a government agency and therefore, cannot regulate or approve labeling for meeting governmental requirements for labels.

How often is my product tested?
Products will be tested based on the schedule that is outlined by the assigned Risk Assessment Category.

Category A:
Brands that are assigned to Category A in their Risk Assessment must submit their products for testing once every three years. All new products must also be submitted for certification during this period.

Frequently Asked Questions [2]

Category B:
Brands that are assigned to Category B in their Risk Assessment must submit their products for testing once every two years. All new products must also be submitted for certification during this period.

Category C:
Brands that are assigned to Category C in their Risk Assessment must submit their products for testing once a year. All new products must also be submitted for certification during this period.

Category D:
Brands that are assigned to Category D in their Risk Assessment must submit their products for testing once a year or as often as required to address all non-conformance issues to an acceptable level.

What testing methods does The Paleo Foundation require?
The Paleo Foundation provides Grain-Free brands with a list of approved testing kits and requires the use of an independent ISO 17025 accredited lab to conduct testing for gluten, and gluten or gliadin competitive.

When do I find out what my Risk Assessment Category is?
The Paleo Foundation will provide your Relative Risk Assessment Category upon receiving the gluten, or gluten/gliadin-competitive results for your products from the independent lab.

Do individual ingredients need to be tested?
No, ingredients do not need to be tested once the final product has been found to meet the requirements of the program.

Frequently Asked Questions [3]

Can Grain-Free Certified products be sold in other countries?
While the Grain-Free Certified program is not a replacement for food safety standards or laws of another country, the Grain-Free logo is trademarked in other countries. Please let the Paleo Foundation know which countries you plan to sell certified Grain-Free products in so that they may ensure that the trademark is protected.

When do I find out what my Risk Assessment Category is?
The Paleo Foundation will provide your Relative Risk Assessment Category upon receiving the gluten, gliadin, and gliadin-competitive results for your products from the independent lab.

Do Ingredients need to be tested?
No, ingredients do not need to be tested once the final product has been found to meet the requirements of the program.

What if I change my ingredients or suppliers?
To add or remove ingredients or suppliers requires prior authorization from The Paleo Foundation.

What if I add or change manufacturers?
To add or change suppliers will require a signed affidavit from the manufacturer to adhere to the requirements as set forth in the Relative Risk Assessment. An additional lab test may be required to ensure that the final product adheres to the standards for gluten, gliadin, and gliadin competitive.

Will The Paleo Foundation share my ingredient or supplier information?
No, for confidentiality reasons, The Paleo Foundation will not share ingredient or supplier information with other brands unless the supplier is certified by The Paleo Foundation, whose certified ingredients are maintained in The Paleo Foundation directories.