

GRAIN FREE STANDARDS

Grain-Free[®] Standards

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Grain-Free Certification Standards 2024.
Standards. The Paleo Foundation.

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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.

Diet Tolerability

The Four major factors that influence the tolerability of a Grain-Free Diet on an individual level:

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



PROGRAM STANDARDS AND SPECIFICATIONS 2024

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1. Grain-Free Certified

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 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

Promotional Materials. 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 **Display.** Producers may display the Grain-Free Certified label only on products that have been certified by The Paleo Foundation.

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

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

1.2.5 **Logo Placement.** If the entire product line has been audited and Grain-Free Certified, producers may display the label on their entire website. 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. 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 **Affadavit.** 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 **Inspection and Audit.** 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 **Authorization.** The Paleo Foundation retains the right to inspect the producer's products to verify that all requirements are met.

1.3.4 **Prohibited Use.** 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.** Misuse of the Grain-Free Certified Label will result in immediate suspension of the agreement and/or prosecution.

1.3.6 **Orientation.** The Grain-Free Certified label must be :



- ① Upright
- ② Complete
- ③ Clearly Visible

2. Grain-Free

2.0.1 **Grains.** 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	Triticosecale rimpaui	Grain
Wheat	Triticum aestivum	Grain
Wild Rice	Zizania spp.	Grain

3. Gluten and Gliadin-Free

3.0.1 **Allowed Gluten and Gliadin Content.** 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.

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Grain-Free Certified Standards for products,
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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 Risk Assessment outlined herein.

Risk Category

The Paleo Foundation will determine a product's Risk category based on the projected level of risk for grain and gluten contamination. The Risk Category is categorized by a number of factors and will determine the Testing Schedule for each product. Manufacturers and Co-Manufacturers must be responsible for upholding the requirements of the assigned Risk Category through ongoing on-site surveillance. The Paleo Foundation reserves the right to change a product's Risk Category in the event of a positive test for gluten and/or gliadin contamination.

The risk category will be determined at the end of the auditing process and assessed as follows:

Risk Category 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.

Risk Category B: The product contains ingredients that have been determined to be low risk for 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.

Risk Category 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.

Risk Category 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.

Testing Schedule

Category A: Brands that are assigned to Category A in their Risk Assessment are not required to resubmit products for testing until the end of the licensing period.

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 every 6 months, or as often as required to address all non-conformance issues to an acceptable level.

Important Note: All new products to be submitted for certification must be lab-tested and assigned a category.

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 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 co-manufacturers can meet all of the Manufacturer's Requirements outlined herein before permissions for Grain-Free certification will be provided.

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 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 Risk Assessment
- Lab reports indicating that the requirements of the program have been met

Manufacturing Requirements

Certification is a process that affects all levels of policies and procedures for a product. The Manufacturing Requirements are outlined herein. The signor must ensure that each requirement herein is met.

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

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

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

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

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

Purchases. The Manufacturing Facility must maintain records of purchasing for all materials used in the production of Grain Free certified products.

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

Batch Records. 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.

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

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, the Auditing Team will review the determination of Grain-Free Certification eligibility. 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-ingredient 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 Risk Assessment.
- An ingredient supplier refuses to offer documentation during the first round of audits.

Disallowed Ingredients: If 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: If 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 manufacturing facility
- Positive swab tests

Packaging Non-conformance: The Grain-Free logo may only appear on products approved by The Paleo Foundation. However, if the label was printed erroneously on a package, the brand will be permitted a feasible period to remove the logo from the product packaging.

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 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 Paleo Foundation may issue a new 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 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.

Frequently Asked Questions

Do I need 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 testing methods does The Paleo Foundation require?
The Paleo Foundation requires the use of an independent ISO 17025 accredited lab to conduct testing for gluten, and gluten or gliadin competitive.

What are the testing requirements for the Grain-Free Certification 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 to meet governmental requirements for labels.

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

Frequently Asked Questions

When do I find out what my Risk Assessment Category is?

The Paleo Foundation will provide your Risk Assessment Category upon receiving the gluten 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?

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.