Where Food Comes From Gluten Free Standards

Where Food Comes From Gluten-Free Standard

1. Introduction:

Where Food Comes From, Inc (WFCF) has issued Version 2.0 of the Certified Gluten-Free Standard to continue to address the growing market need to assist consumers in making informed dietary choices in the foods they purchase and consume, particularly with regard to food products that may contain gluten proteins. Increasing numbers of consumers find that they have a greater degree of sensitivity (sometimes but not always referred to as Celiac disease) when eating foods that typically contain these types of proteins, and as such wish to limit or eliminate their intake of them. Manufacturers and brands may use this Standard to label products in the market as Certified Gluten-Free.

Compliance with this Standard is based on a combination of quantitative analysis of the products being marketed as Certified Gluten-Free, along with required management practices aimed at minimizing the introduction (accidental or

otherwise) of gluten proteins in the production system of a particular food item. Analytical testing is also required, and although it is not an absolute guarantee of zero gluten molecules in any given product, the strict limit of detection for testing assures that any present gluten would be below that currently allowed by the FDA for a gluten-free claim.

This combination of practices and testing creates a formidable program under which purchasers of Certified Gluten-Free products can rest assured they can have confidence in the products bearing this seal. Correspondingly, this Standard also sets guidelines and requirements for what kinds of claims (labeling and otherwise) may be made related to the certification.

Where Food Comes From welcomes comments on this Standard at any time. Comments and questions may be forwarded to info@WFCFwherefoodcomesfrom.com.

2. Definitions

(a) Celiac disease - a medical condition in which the absorptive surface of the small intestine is damaged by a substance called gluten. This results in an inability of the body to absorb nutrients: protein, fat, carbohydrates, vitamins and minerals, which are necessary for good health.[1]

(b) Gliadin - a fraction of the gluten protein that is found in wheat and rye and to a lesser extent in barley and oats. Its solubility in diluted alcohol distinguishes it from another grain protein, glutenin.[2]

(c) Gluten –

- a protein fraction from wheat, rye, barley, oats or their crossbred varieties and derivatives thereof, to which some people are intolerant and that is insoluble in water and 0.5 M NaCl'[3]; *or*
- certain proteins that occur naturally not only in wheat, but also in rye, barley, and crossbreeds of these grains and that can harm people who have celiac disease.[4]
- A mixture of two proteins, gliadin and glutenin.[5]

(d) Glutenin - a simple protein of cereal grains that imparts adhesive properties to flour.[6]

(e) Handle – to conduct any form of post-harvest movement, storage, transformation, packaging, and/or labeling of goods along the entire chain of

[1] Canadian Celiac Association - http://www.celiac.ca/celiac.php
[2] http://medical-dictionary.thefreedictionary.com/gliadin
[3] Codex Alimentarius Commission: Draft revised standard for gluten-free foods, Step 8. [http://www.codexalimentarius.net/web/archives.jsp?year=08] *ALINORM 08/31/26* 2008.
[4] US Food and Drug Administration: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm265212.htm
[5] http://www.thefreelibrary.com/Coeliac+Disease-Information+on+Coeliac+Disease-a01073870984
[6] http://dictionary.reference.com

custody from seed to consumer, except for products enclosed in final retail packaging.

3. Scope

3.1. Products

Products compliant with this Standard must be produced without the inclusion or introduction, accidental or otherwise, of the following ingredients or their derivatives:

- Wheat
- Varieties and derivatives of wheat such as:
    - Wheatberries
    - Durum
    - Bulgar
    - Emmer
    - Semonlina
    - Spelt
    - Farina
    - Farro
    - Graham
    - Khorasan wheat (aka. Kamut®)
    - Einkorn wheat
- Spelt
- Rye
- Triticale
- Barley
- Brewer's Yeast
- Malt in various forms including: malted barley flour, malted milk or milkshakes, malt extract, malt syrup, malt flavoring, malt vinegar
- Wheat Starch that has not been processed to remove the presence of gluten to below 10ppm and adhere to the FDA Labeling Law

Products certified under this Standard may be single ingredients or multi-ingredient formulations. They may be sold in non-retail and/or retail forms. This includes supplements and vitamins.

3.2 Operators

Any supply chain operator who handles agricultural, food, vitamins, supplements and other such materials may apply for certification against this Standard, including:

- Processing, manufacturing, and/or packing operations, including bakeries, restaurants, and other food-service or retail establishments;
- Storage, warehousing, and/or transport operations;
- Brokers, traders, and/or brand owners.

Certification of operators is dependent upon the verification of compliance with this Standard at each and every site of operation that physically produces or handles ingredients or products claimed as certified.

4. Ingredients

4.1 Ingredient Specifications - Ingredient purchasing specifications that require attestation regarding the potential or actual gluten content of the materials being obtained must be in place.

(a) In particular, these specifications must:

i. Require the supplier to state whether any of the ingredients supplied are intended to contain any of the ingredients mentioned in §3.1, or their derivatives, and if so, which one(s). If there is an affirmative answer with respect to any such material as mentioned in §3.1, the ingredient may not be used toward compliance with this Standard.
ii. Require the supplier to state if the ingredients supplied are handled by an operation that also handles any of the ingredients mentioned in §3.1 (including harvest and storage of the material at farm sites), or their derivatives, and if so, which one(s). If such materials as referenced in §3.1 are handled, the measures in place to assure separation between those materials and the ones being purchased pursuant to compliance with this Standard.
iii. Require that the ingredients be transported from the supplier in a manner that minimizes risk of their being contaminated by gluten molecules, including but not limited to restrictions on the cleanliness of transport vessels and the integrity of packaging.

(b) Ingredient specifications may:

i. Unless 100% of a product's ingredients can be proven to be free of gluten contamination risk, the Standard requires finished product to be tested. As a result, the supplier of the ingredient(s) in question can provide documentation indicated the grain has been tested for gluten content, and shown to be non-detectable in accordance with the limits and methods set in §7 of this Standard. In such case, the supplier shall specify the method of sampling and analysis. However, this step is not required for the finished product to be Certified Gluten Free.
ii. Attest to their having Gluten-Free content by showing a certificate issued by another standard that certifies claims of absence of gluten, which is deemed by WFCF to be equivalent to this Standard.[7]

[7] WFCF is cognizant of other programs that certify gluten-free production and shall make determinations under this clause on a case-by-case basis. In each case WFCF shall make clear the rationale for its determination.

4.2 Implementation and Documentation - The requirements mentioned in §4.1 must be implemented for every acquisition of ingredients included in any products to be certified under this Standard. Documentation that reflect this must be on file at the certified operation.

5. Handling

5.1 Cleanout of Equipment - Receiving, production, processing, manufacturing, transfer, and storage facilities, as well as shipping and transportation conveyances, shall be inspected and cleaned/purged as needed to remove sources of gluten contamination, and all relevant cleaning, purging, and inspections shall be documented.

5.2 Segregation - If the operation is not dedicated to exclusion of gluten, systematic procedures shall be in place during production to keep compliant inputs, work-in-progress, and finished products separate from all materials that are not compliant with this Standard. If production lines are used for both gluten and gluten free products sufficient flushing and cleaning process must be in place and documented to ensure there is no cross contamination.

5.3 Traceability - Each lot of certified Gluten-Free product or input must be traceable back to specific lot(s) of the inputs used in its production. Traceability records shall explicitly trace and track the compliant status of inputs and final products.

6. Products

6.1 Product Specifications – Each lot of final product must be tested in accordance with §7 of this Standard, and the results documented. The only instance in which finished product testing is not required is if 100% of a product's ingredients can be proven to be free of gluten contamination risk, and the production facilities are proven to have no risk of contamination to the point at which the product is packaged and sealed.

6.2 Packaging - Packaging must be of such construction and materials to prevent contamination by gluten molecules from any source. If packaging is used for ingredients or work-in-progress or another such manner prior to final packaging and is permeable to gluten molecules, testing must be conducted on all such lots of good prior to enclosing in the final container.

7. Sampling and Testing

7.1 Limit of Detection – In order for ingredients and products to be compliant with this Standard, they shall be verified to not contain gluten molecules at a level of detection no less sensitive than 10 parts per million (ppm).

7.2 Method of Detection - Testing must be conducted by immunologically-based methods such as ELISA plate or lateral flow strip tests. Tests must check for the antigens gliadin (R5) and/or glutenin (Skerritt).

7.3 Sampling - A statistically valid sampling and testing plan shall be designed on the basis of risk assessment of the production/handling system and shall reflect the level of monitoring appropriate for the risks inherent in the production/handling system, as well as industry standards. The sampling and testing plan must be approved by WFCF prior to initial sampling for verification.

7.4 Competency and Training – Laboratories external to the operation seeking certification who are contracted for analytical services by the operation in question must be accredited to ISO 17025to perform the analyses specified in §7.1 and §7.2. In-house analysts at certified operations must be trained and their performance verified to assure they use the tests reliably. WFCF reserves the right to evaluate laboratory and protocols as a condition for acceptance.

7.5 Reproducibility – The sampling and testing plan must be sufficiently robust so as to allow for reproducibility of test results. The means of validation of reproducibility shall be described by the entity(ies) performing the analyses and shall be supported by there being adequate material(s) available to allow for repeated testing to be done on any given lot.

7.6 Surveillance / Random Testing – WFCF reserves the right to conduct random and/or risk-based sampling and testing of ingredients and/or products as an additional level of assurance. Certified operators and their involved supply chains shall cooperate with all related requests.

8. Claims and Labeling

8.1 Applicability – Any operator certified under this Standard may make a relevant claim. WFCF determines the relevance of all claims on a case-by-case basis. Labeling claims must be accurate and truthful and must not be misleading the consumer. Claims may relate to specific products or lines of products, or to specific services for handling of certified ingredients or products.

8.2 Logo/Seal Use, On-Product Claims, and Related Marketing Information – All claims, labels and related sales materials and any use of the WFCF logo must be reviewed and approved in writing by WFCF in advance of their release for marketing purposes.
(a) Any promotional, sales, or other descriptive language referring to the guarantee afforded by certification to this Standard shall avoid use of misleading claims, such as the statement that absolutely Gluten-Free molecules exist in the product. Instead,

such guarantees shall refer to the limit of detection afforded by the tests employed as required in §7.
(b) If the limit of detection employed is more sensitive than the limit required in §7 and the operation demonstrates its reliable implementation, this limit may be referenced in labeling and other sales/marketing information.
(c) WFCF may allow certain additional claims that result from the verification afforded by this Standard, for example "wheat free." WFCF shall determine the validity of any such claim on a case-by-case basis.

9. Quality Assurance

9.1 Quality Management System – Each certified operation shall execute a quality assurance and quality control program as needed to assure compliance with this Standard. Conformity with the requirements of the operation's own Quality Management System and this Standard shall be checked on an ongoing and/or periodic basis, as appropriate to insure products certified under this Standard consistently meet the requirements in §7.1. Documentation of this checking and its corresponding follow-up shall be documented. Quality Management Systems based on HAACP or other recognized food safety systems, (ISO22000, GFSI) are preferred.

9.2 Training – All personnel responsible for the production, handling and/or management of Gluten-Free products must be trained in accordance with the Standard and the facility's applicable operating procedures. All training must be documented, and training records maintained on file for a minimum of three years.

9.3 Corrective actions - Non-conformities in processes, procedures, inputs, or products, which could impact compliance with this Standard shall trigger corrective actions.
(a) Major nonconformities are defined as those that indicate a noncompliant ingredient or product (one containing gluten above the limits set in §7.1) has been included in the certified production stream. Each major nonconformity shall be reviewed at the time of occurrence and documented, including but not limited to:

i. Corrective actions to address the immediate problem;
ii. Disposition of all affected or potentially affected ingredients and/or products;
iii. Root-cause analysis; and
iv. Remedial measures undertaken to avoid recurrence.

(b) Minor nonconformities are defined as instances where certified product compliance is not affected, but where improvements are needed to fully meet the letter and intention of this Standard. Minor nonconformities shall be documented and followed up on at least a periodic basis as specified in the Quality Management System in accordance with §9.1.
(c) All certified operations must have a documented product recall in place with mock recalls performed at regular intervals and the results of those mock recalls

available for review. The recall process should take into account the following factors:

(i) Results of health hazard evaluation
(ii) Ease in identifying the product
(iii) Degree to which the product's deficiency is obvious to the consumer or user
(iv) Degree to which the product remains unused in the market-place
(v) Continued availability of essential products

10. Documentation Requirements

10.1 Additional Documents - In addition to the documentation required elsewhere in this Standard, all certified operations must maintain the following records:
(a) Complaints received about products– especially concerning actual detection or suspicion of gluten presence in a product (or products). All complaints must, at a minimum and in addition to more detailed records on each case, be logged in summary fashion, showing at least the following:

i. The name of the complaining party;
ii. The date the complaint was received;
iii. The nature of the complaint; and
iv. The response by the certified operation to the complainant; and
v. Any corrective actions made.

(b) All certified operation must have a customer complaint process related to products certified under this Standard. This process must analyze and evaluate complaints in order to improve the quality of the products.

10.2 Retention and Availability – All documents involved with demonstrating compliance with this Standard shall be retained by the certified operation for a minimum of five years from the date of their generation. Records must remain sufficiently accessible and legible that WFCF personnel may review them upon request.

11. Inspection and Verification

11.1 Frequency – Certification is valid for a one-year cycle, the anniversary date of expiry of the certification being on the date that initial certification is granted.

11.2 Application and Updates – Initial application for certification must include all information requested by WFCF for review prior to scheduling a site visit. The certified operation shall update this information at least annually, sufficiently in advance of the anniversary date to allow WFCF personnel to make the relevant review.
(a) Significant changes to an operation must be reported to WFCF in advance of their actual implementation to allow appropriate review and approval. Significant changes include but are not necessarily limited to:

i. Addition of new products;
ii. Addition of new facilities or processing lines;
iii. Change in production site(s); and
iv. Change in key management personnel.

11.3 Surveillance – WFCF helps assure the credibility of its programs by conducting ongoing surveillance of certified operations and products in the marketplace. Certified operators must be cooperative and responsive to related requests, including but not limited to:
(a) receiving and cooperating with inspectors at unannounced visits;
(b) providing additional information requested by certification staff; and
(c) responding to nonconformities WFCF raises through its market surveillance or receipt of information from various sources.