

TECHNICAL STANDARD FOR THE CERTIFICATION OF **GLUTEN FREE PRODUCTS**

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GLUTEN FREE



VERY LOW GLUTEN

1. PURPOSE AND FIELD OF APPLICATION

The purpose of this document is to define the requirements for the certification of foods that are gluten-free or have very low gluten content and which are suitable or specifically formulated for people with gluten intolerance.

The certification applies to the following products that meet the requirements of this standard:

- food products, food supplements, ingredients for the food industry;
- products and gastronomic preparations obtained in businesses and catering activities;
- pet-food.

2. OBJECTIVES AND ADDED VALUE OF CERTIFICATION

Gluten refers to a family of proteins known as prolamines (mainly glutenin and gliadin) that make up the storage protein in starchy endosperm of many cereals such as wheat, barley, and rye. Each type of cereal contains different amounts of gluten and other proteins. A beneficial feature of gluten proteins is their viscoelasticity, which lends itself to the production of tasty dough and bread products.

Cereals containing gluten, such as wheat, make up much of the modern Western diet. This is, in part, due to their palatability, ease of cultivation and processing into a wide variety of foods, large-scale production capacity and high nutritional content.

Glutenin and gliadin contained in gluten must be digested in the small intestinal lumen after consumption. They are long peptide molecules difficult to digest for humans and are rich in two amino acids: proline and glutamine.

New gluten peptides may come from genetic modification resulting from modern agricultural practices. In foods more immuno-activating gluten peptides can be observed. Gluten-derived peptides, such as gliadin and glutenin in wheat, but also secaline in rye and ordein in barley, have been identified as important antigen-producing proteins in celiac patients.

An important right for people suffering from celiac disease is to have clear information on foods about their suitability for a gluten-free diet. The Reg. CE No. 41 of 2009, replaced by Reg. EC N° 828 of 2014, currently in force, established the conditions of use of the words "gluten-free" which guarantee celiacs, both on packaged products and on those sold in bulk, a maximum content of 20 mg/kg of gluten.

The company that indicates its food product as "gluten-free" must therefore guarantee both the absence of ingredients containing gluten, but also the absence of the danger of contamination.

Furthermore, the EC Reg. No. 828/2014 established that the wording "gluten-free" can be followed by the indications "specifically formulated for celiacs - people intolerant to gluten" or "suitable for celiacs - people intolerant to gluten".

The first wording can only be used for foods where the gluten, traditionally present, is reduced or replaced (bread, pasta, biscuits, etc.). The use of the wording is voluntary, but it becomes mandatory for products included in the National Register of gluten-free foods (RNA), made available to celiac people by the National Health Service (NHS).

The words "suitable for celiacs - people intolerant to gluten" can, instead, be used for any food, always in combination with "gluten-free", provided that the absence of raw materials containing gluten and the absence of contamination is guaranteed.

The only prohibition is on all foods that never contain gluten (e.g., water or traditional cheeses), so the claim would be superfluous and potentially misleading for the consumer, that would be led to believe that only products with the wording were suitable, when instead the whole category is suitable for celiacs.

Cereals containing gluten, such as wheat or barley, are considered allergenic within the meaning of the European Regulation (Reg. 1169 of 2011). According to this Regulation (Article 9), all food business operators are required to declare the presence - in the finished product - of allergens used in the preparation of a food

and still present in the finished product, whether it is a packaged food, whether it is a dish served in a restaurant.

On the other hand, the European legislator has not yet regulated the words "*may contain ...*" and, at the moment, its absence does not offer the same guarantees as the use of the "gluten-free" claim.

This standard and the system of product certification and of production process certification is a tool for the implementation of best production practices and is subject to regular consultation of stakeholders also within the review processes.

Certification allows manufacturers to ensure the conformity of their products and make credible statements to consumers.

The mark is granted exclusively to companies that are subject to specific controls carried out by BAC and that obtain certification of compliance with this standard.

3. DEFINITIONS

- **Applicant:** Operator requesting certification.
- **Licensee:** Operator to whom the certificate of conformity is issued.
- **Gluten:** the protein fraction of wheat, rye, barley, oats or their crossed varieties and their derivatives, to which some people are intolerant and which is insoluble in water and in 0,5 M sodium chloride solution;
- **Wheat:** all species of Triticum.
- **Accidental contamination:** the unintentional addition of gluten to the food that is free of it, due to accidental and unwanted events and, therefore, not controllable. Accidental contamination usually determines the presence of traces of gluten in the food ready for consumption, in quantities at the limit of instrumental detection (ppm or ppb).
- **Cross-contamination (cross-contamination):** accidental contamination due to the "crossing" of gluten-free product with gluten product throughout the production chain, from the collection of raw materials to the delivery of packaged or bulk food to the consumer.
- **Environmental contamination:** accidental contamination due to incorrect behaviour, for example, by consumers during storage and preparation at home or in catering facilities, for incorrect behaviour and uncontrolled environmental conditions.
- **Raw material:** food matrix including ingredients, additives, flavourings and processing aids used for the preparation and processing of food products.
- **Traceability:** the possibility of reconstructing and following the path of a food, feed, animal destined to food production or substance intended or likely to become part of a food or feed at all stages of production, processing and distribution (Reg. CE 178/2002).

4. REGULATORY REFERENCES

- CODEX ALIMENTARIUS ([special food standard for people intolerant to gluten CXS 118-1979](#)) adopted in 1979.
- [COMMISSION IMPLEMENTING REGULATION \(EU\) No 828/2014 OF 30 July 2014 ON THE REQUIREMENTS CONCERNING INFORMATION FOR CONSUMERS ON THE ABSENCE OF GLUTEN OR ITS PRESENCE TO A LIMITED EXTENT IN FOODS. THE COMMISSION HAS ADOPTED THIS REGULATION.](#)
- [REGULATION \(EU\) No. 1169/2011](#) of 25 October 2011 on the provision of food information to consumers.
- [Federal Register Notice for Final Rule for Gluten-Free Labeling of Fermented or Hydrolyzed Foods](#)
- [Federal Register Notice for the Gluten-Free Labeling Final Rule](#)

- [Guidance for Industry: Gluten-Free Labeling of Foods; Small Entity Compliance Guide](#)
- UNI CEI EN ISO/IEC 17065 - Conformity assessment requirements for bodies that certify products, processes and services.
- UNI CEI EN ISO/IEC 17025 - Accreditation of tests and calibrations.

The references above are those in the version in force at the time of issue of this document. In any case, the regulatory references in the version in force at the time of the development of the certification activity must be applied.

5. CERTIFICATION REQUIREMENTS

5.1 PRE-REQUIREMENTS (authorizations)

The applicant operator must have all mandatory food safety authorizations. When necessary, the site must be registered as a producer of special foods (registration with the Ministry of Health)¹.

5.2 SPECIFIC REQUIREMENTS FOR GLUTEN-FREE AND VERY LOW GLUTEN PRODUCTS

- **GLUTEN-FREE food "suitable for people intolerant to gluten" or "suitable for celiacs"**
Food whose content does not exceed 20 mg/kg (20ppm).
The operator should put the words "gluten-free" on the product in order to make it clear to the consumer that the product is gluten-free or that the amount of gluten contained in the product is below the minimum threshold indicated above.
The wording "suitable for people intolerant to gluten" or "suitable for celiacs" may accompany the indication.
- **GLUTEN-FREE food "specifically formulated for people intolerant to gluten" or "specifically formulated for celiacs"**
Food that would include a cereal (or other ingredient) containing gluten as the sole or predominant ingredient that is replaced with other gluten-free ingredients or where the gluten content is reduced below the minimum threshold of 20 ppm (20 mg/kg).
The operator should put the words "gluten-free" on the product in order to make it clear to the consumer that the product is gluten-free or that the amount of gluten contained in the product is below the minimum threshold indicated above. The wording "specifically formulated for people intolerant to gluten" or "specifically formulated for coeliacs" may accompany the indication.

⁽¹⁾ In Italy, with the decree of 17 May 2016, the deliverability of "gluten-free" foods specifically formulated for celiacs (formerly dietetic) was maintained. Then, with the decree of 10 August 2018, the expenditure ceilings were updated (distinguished by gender and by age group, on the basis of the 2014 LARN), and the deliverability was maintained only for foods intended to replace those traditionally characterized by the presence of cereals source of gluten.

Pursuant to the Ministerial Decree of 17 May 2016, in order to obtain its deliverability, operators in the food sector have the right to notify the Ministry of Health of gluten-free foods specifically formulated for celiacs falling within the categories defined by article 2 of the Ministerial Decree of 10 August 2018.

When the OSA requires the deliverability, the food must completely report the wording "gluten-free food specifically formulated for celiacs (or for people intolerant to gluten)" every time the absence of gluten is referred to on the label of the food itself.

- **VERY LOW (OR LOW GLUTEN) GLUTEN FOOD**

Food consisting of one or more wheat ingredients (that is, all species of Triticum, *such as* durum wheat, spelt and Khorasan wheat, also marketed under different brands such as KAMUT), rye, barley, oats or their crossed varieties, which have been specially developed to reduce the gluten content to a level of between 20 and 100 mg/kg in total.

5.2.1 ADDITIONAL REQUIREMENTS FOR FOODS CONTAINING OATS

Oats contained in a food presented as "Gluten Free" or "with a very low gluten content" must have been specially produced, prepared and/or processed so as to avoid contamination by wheat, rye, barley or their crossed varieties and its gluten content must also not exceed 20 mg/kg (20 ppm).

PLEASE NOTE: Where rules are in force in the country of destination that provide for lower accidental contamination limits than those mentioned above, the applicant operator shall ensure compliance with those limits and, more general, with any more restrictive "gluten-free" labelling provisions.

5.2.2 QUALIFICATION OF RAW MATERIAL SUPPLIERS

Raw materials must come from approved suppliers on the basis of a careful risk assessment.

The applicant operator shall evaluate in advance all raw materials used in "gluten-free" recipes to determine the presence and chance of gluten contamination.

Raw materials shall be classified according to the following criteria:

- a) **FORBIDDEN:** all products containing, deriving or consisting, even in part, of durum wheat, soft wheat, barley, spelt, kamut, rye, triticale, spelt, oats that have not undergone any type of treatment;
- b) **EXEMPT:** raw materials as they are or semi-finished products naturally gluten free; by way of example, fruit, vegetables, meat, milk and dairy products (butter, cheese, whey powder, etc.) may be included in this category, as well as additives and processing aids which are not derived, do not contain or consist of durum wheat, soft wheat, barley, spelt, kamut, rye, triticale, spelt, oats.

They may be used freely after an assessment of the risk of cross contamination has been made at the sellers' sites.

For semi-finished products composed of several ingredients, the technical data sheet for conformity assessment shall be taken into account. For all doubtful cases it will be necessary to proceed as for raw materials at risk;

- c) **CRITICAL:** are raw materials or semi-finished products that by composition or accidental contamination may contain gluten.

These products can only be used after acquiring, for each batch, a certificate of analysis. Prohibited cereal derivatives (e.g., swallowed starch) or other raw materials may be used as risk raw materials, provided that they are used in the finished product to a gluten content of not more than 20 ppm.

In this case the finished products should be evaluated analytically for each batch.

The use of raw materials certified according to standards and certification programs deemed equivalent by Bioagricert is allowed, provided the formulation allows compliance with the limit of 20 ppm.

5.3 GLUTEN RISK ANALYSIS

The applicant operator shall have an effective and operational food safety plan based on the HACCP principles of the Codex Alimentarius.

This plan shall include:

- a) an assessment of the risk of presence of gluten in raw materials;
- b) an assessment of the risk of cross-contamination at all stages of production;
- c) the planning of the management of the most relevant and critical steps for hygiene safety in general and for the absence of gluten in the final product;
- d) the controlled management of the most relevant and critical phases of the process entrusted to adequately trained and aware personnel.

The applicant operator shall have developed a system for the management of other allergens that minimizes the risk of contamination of the products and that meets legal labelling requirements. In case of doubt, indicate the residual risk on the label.

The applicant operator must make available a list of allergens presents on the "Gluten Free" production site e and its Self-control manual must include the risk assessment.

The packaging material must be suitable for the required use and the storage must take place under conditions that reduce contamination and deterioration.

The applicant operator shall entrust external accredited laboratories with analyses that are critical to confirm the safety, legality and quality of the products.

In addition, the applicant operator must carry out a specific assessment of the voluntary "risk of sabotage" with cereal derivatives in gluten-free production.

This analysis shall take into account:

- a) company climate (personnel and related issues);
- b) easy to find product containing gluten at the company;
- c) points of possible sabotage.

5.4 REQUIREMENTS FOR THE PRODUCTION SITE

The production site of the applicant operator must ensure structural conditions to avoid and prevent gluten contamination from external sources (e.g., away from mills, other production sites using flour with silos outside).

The manufacturer must, in justified cases, take segregation measures (air filtration, closing of doors/windows, overpressure).

The operator should preferably dedicate the plant and its processing lines to gluten-free production.

When the operator uses the same production lines and equipment for both conventional and "gluten-free" production, it must follow the following operations:

- 1) it must clean the plant thoroughly before any "gluten-free" production;
- 2) it must eliminate a first aliquot of gluten-free product or it must sell it as a conventional product; the quantity of product to be discarded shall be defined on the basis of a documented validation.

Dust extraction systems, if they exist, must preferably be separated or alternatively designed in such a way that there is no dust recirculation; filter cleaning must be carried out away from production lines or in the absence of "Gluten Free" raw materials, semi-finished and finished products;

The operator must keep separate at all times all raw materials, semi-finished and finished products included in the certification from conventional products.

The operator must guarantee separation as to exclude any possibility of contamination of the product during any stage of the storage, production and distribution processes.

The operator must not store any risk materials in open containers in the same warehouse where it keeps semi-finished products or raw materials.

In the case of establishments not dedicated to gluten-free production, the operator must guarantee that the changing rooms for personnel involved in gluten-free production are separated or it should make available a place for changing the clothing or disposable clothing before entering the gluten-free production area.

In any case, the clothing of the personnel dedicated to gluten-free production must be differentiated and recognizable.

When staff are employed in both gluten and gluten-free units, they must have separate changing rooms or lockers, or their gluten-free clothing must be renewed at each entrance (acceptable the use of disposable clothing of different color); before entering the area dedicated to gluten-free production, personnel must wash hands, clean the sole of shoes or use overshoes.

For the last phase of hand washing, it is recommended to use ethyl alcohol (gliadin inhibitor).

The operator must entrust to specialized laundries the washing of clothing and it must formally inform them that the company produces gluten-free food.

Alternatively, the staff may use disposable protections including overshoes, gowns or (preferably) full protective suit and headgear.

5.5 TRACEABILITY

The operator shall ensure, for each batch produced, traceability of the batch number and of the producers/suppliers of the critical ingredients and other components.

Criticality is related to likely gluten content/contamination. The operator shall test the traceability system once a year by simulating a recall of the product. The operator must adequately train the traceability system manager on the procedures implemented for the management of the "gluten-free" requirements.

5.6 TRAINING OF STAFF

Personnel involved in the production of gluten-free products must receive specific training on gluten and coeliac disease (in addition to compulsory training by law).

The operator must record the training on a personnel file and must verify the comprehension of the topics explained; the operator can engage new staff in the relevant and critical phases of the production process only after providing suitable training.

5.7 SPECIFIC REQUIREMENTS FOR CATERING ESTABLISHMENTS

- a) Canteens of collective catering, as well as all centers of commercial catering, must guarantee the production of foodstuffs, dishes or menus obtained with the exclusive use of:
 - "Gluten-free" diet foods with ministerial notification according to D. Lgs. 111/92, contained in the National Food Register of the Ministry of Health (requirement valid for Italy) or have other permits in accordance with the provisions of other EU Member States;
 - "Gluten-free" foodstuffs certified on the basis of this standard or other standards and certification programs deemed equivalent by Bioagricert.
 - Naturally gluten-free food whose production chain and marketing does not present any risk of contamination with gluten (e.g., fruit and vegetables, meat, etc.).
- b) Food preparations and all foodstuffs must guarantee a gluten content of not more than 20 ppm.
- c) The operator must guarantee traceability of the individual batches of the ingredients constituting the gastronomic preparation served daily.
- d) The operator must employ staff trained specifically for the provision of the service and must monitor and regularly update their skills and performances.
- e) The operator must take appropriate measures to prevent cross-contamination and environmental contamination.

6. METHODS OF CONTROL

6.1 INITIAL ASSESSMENT

A) CONFORMITY OF PRODUCTION UNITS/SUBCONTRACTORS USED

BAC verifies the data and documents relating to production, packaging and labelling units, to assess compliance with the most significant (mandatory) law requirements and with the requirements of this standard applicable to the specific production process.

B) CONFORMITY OF PROPOSED FORMULATIONS

At the start-up stage or in case of a request for extension of the certification scope (new products), BAC verifies the recipes of the products for which certification is required, the technical sheets of the raw materials/ingredients deemed critical, labels and other communication material.

BAC reserves the right to assess the conformity of the labels and claims regarding the gluten-free requirement.

C) TECHNICAL REPORT (or company quality plan)

The operator must indicate all the special measures that the company will take to ensure compliance with the requirements imposed by the standard for the products subject to certification, compared to the normal conduct of the production process.

6.2 NUMBER/ FREQUENCY OF INSPECTIONS

At the beginning of the certification, BAC carries out inspections at the Operator's production plant in addition to any subcontractors or third parties where it is necessary to check the compliance to the requirements of this standard. BAC defines the number and type of plants checked in relation to the criticality of the sites and activities carried out.

BAC will carry out subsequent monitoring audits at least annually and it will define the control and analysis plan on the basis of a careful risk analysis.

BAC reserves the right to carry out additional (even unannounced) inspections and/or to intensify the surveillance activity in case of serious non-conformities found in the context of normal controls or reported by other stakeholders.

6.3 ELEMENTS SUBJECT TO BAC VERIFICATION

During the inspection at the applicant's premises, BAC will assess all aspects of the quality system applicable to the production of the product as it is summarized in the following list:

1. Quality System related to the product/process/service
2. Control of documents and data
3. Supplies and and qualification of suppliers
4. Product identification and traceability
5. Process control
6. Tests and analysis
7. Inspection of the non-conforming product
8. Corrective and preventive actions
9. Handling, storage, packaging and delivery
10. Control of quality records

- 11. Internal audits concerning quality
- 12. Training
- 13. Complaints
- 14. Management review

6.4 ANALYTICAL TESTS

The Operator, on the basis of critical aspects of its own production process and product composition, must prepare an adequate analysis plan within its self-control system.

Bioagricert will verify the correctness and effectiveness of this plan, including sampling and analysis carried out by qualified laboratories.

Both Bioagricert and the applicant Operator must use accredited tests based on EN 17025.

The Codex standard requires the ELISA R5 with the Mendez method for the determination of gluten. For the detection of hydrolyzed gluten (e.g.: beer, syrups, etc.) a variant of the "sandwich" R5 ELISA must be applied: the "competitive" R5 ELISA.

7. PROCEDURES FOR THE DECLARATION OF CONFORMITY

The communication of the "Gluten Free" certification must always clearly refer to food products and gastronomic preparations subject to certification.

The Licensee Organizations, once obtained the certificate of conformity, for products in the category "Gluten Free" (gluten < 20 ppm) may use the certification marks provided for the specific type of product: "Gluten Free" and "Very low gluten content".

Certification marks must comply with the following colours (blue/green, B/W or grayscale. Any other combination must be previously authorized by BAC).

The mark on the label must be clearly visible and identifiable by the consumer.

