

GUIDANCE Gluten-Free Labelling

May 2025



Table of Contents

Introduction	1
Disclaimer	1
Context	1
Definitions & Scope	2
Definitions	2
Relevant Legislation	3
Gluten Statements and Labelling as Defined by the 'Gluten-Free' Regulation	6
Definitions of Statements	6
Information to Consumers About the Absence or Reduced Presence of Gluten in Food	7
Oat - A Specific Case	9
Food Business Operators' Responsibility: Risk Management & Communication	10
How to Ensure Compliance?	11
Wheat Labelling as Allergen in a Gluten-Free Product	13
Position on the Label	14
Use of Gluten-Free Logos and Symbols	14
Notification	15
Terminology	16

Introduction

Disclaimer

This guidance document is intended to provide Specialised Nutrition Europe (SNE) members and Food Business Operators with information on the EU regulation concerning gluten-free foods and food low in gluten and is for general information purposes only. The information contained herein does not constitute legal or other professional advice. SNE and its members accept no responsibility or liability to users or any third parties in relation to the use of the information contained in this guidance.

The content of this guidance is the copyright of SNE. You may not republish or distribute information contained in this guidance for any commercial purpose without prior written consent, which can be requested by contacting SNE at s@specialisednutritioneurope.eu.

Context

Commission Implementing Regulation (EU) 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food entered into force on 20 July 2016 and is based on Regulation (EC) 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to a gluten, which was repealed by Regulation (EU) 609/2013 on foods for specific groups.

It is important to note that foods covered by Commission Regulation (EU) 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control - so-called Regulation on Foods for Specific Groups (FSG Regulation) still have specific requirements for statements related to gluten.

Definitions & Scope

Definitions

- **‘Gluten’** means a protein fraction from wheat, rye, barley, oats or their crossbred varieties and derivatives thereof, to which some persons are intolerant, and which is insoluble in water and 0,5 M sodium chloride solution (article 2.a of Regulation (EU) 828/2014).
- **‘Wheat’** means any Triticum species (article 2.b of Regulation (EU) 828/2014) Wheat (i.e. all Triticum species, such as durum wheat, spelt, and khorasan wheat), rye and barley have been identified as grains that are scientifically reported to contain gluten. The gluten present in those grains can cause adverse health effects to people intolerant to gluten and people with coeliac disease (who suffer from a permanent intolerance to gluten), and therefore its consumption should be avoided by such people. (Recital 1 of Regulation (EU) 828/2014).
- **‘Coeliac disease’** Coeliac disease is not defined per se in the EU Regulation.

SNE Interpretation

The Codex Alimentarius General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) defines Coeliac disease as a chronic immune-mediated intestinal disease in genetically predisposed individuals induced by exposure to dietary gluten proteins that come from wheat, rye, barley and triticale (a cross between wheat and rye).



Allergy to wheat and coeliac disease are two distinct diseases. When a person is allergic to wheat, the immune system exhibits an abnormal reaction to wheat proteins and exhibits symptoms similar to those caused by other food allergies. The only way to manage wheat allergy is to completely avoid the allergen involved.

Relevant Legislation

Food Information to Consumers (FIC) – Regulation (EU) No 1169/2011

Voluntary food information

Article 36.2 of Regulation (EU) No 1169/2011 stipulates that voluntary declarations such as ‘Gluten-free’ or ‘Very low gluten’ may only be provided if they comply with the following requirements:

- they shall not mislead the consumer;
- they shall not be ambiguous or confusing for the consumer;
- they shall, where appropriate, be based on the relevant scientific data.

Allergen Labelling

As stipulated in article 9.1 (c) of the FIC Regulation, the indication of any ingredient (...), even if in an altered form, is mandatory. Annex II of the FIC Regulation lists the substances or products containing gluten as causing allergies or intolerances (e.g. cereals containing gluten).

The EU Regulation defines cereals containing gluten as: wheat, rye, barley, oats, spelt, kamut or their hybridised strains, and products thereof. However, it does exclude:

- a) wheat based glucose syrups including dextrose¹;
- b) wheat based maltodextrins²;
- c) glucose syrups based on barley;
- d) cereals used for making alcoholic distillates, including ethyl alcohol of agricultural origin.

The requirement for mandatory indication of allergen applies even where the final food carries statements as foreseen under the gluten-free foods regulation (Regulation 828/2014).

¹ And the products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by the Authority for the relevant product from which they originated.

² Idem.

Processed Cereal-based Foods and Baby Foods for Infants and Young Children – Directive 2006/125/EC

Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children requires that the presence or the absence of gluten must be indicated when the product is intended for infants below six months of age. The absence of gluten in processed cereal-based foods and baby foods for infants and young children must be indicated in accordance with the requirements laid down in Commission Implementing Regulation (EU) No 828/2014.

Infant Formula and Follow-on Formula – Regulation (EU) 609/2013

Compositional and information requirements related to infant formula and follow-on formula are set out in Regulation (EU) No 609/2013 (and Annex I and II of the delegated regulation (EU) No. 2016/127) which stipulates that **the use of ingredients containing gluten is not permitted** in the production of infant formula and follow-on formula. Commission Implementing Regulation (EU) No 828/2014 (Article 4) specifically prohibits the provision of information on the absence or reduced presence of gluten in infant formulae and follow-on formulae.

Foods for special medical purposes (FSMP) – Regulation (EU) 2016/128

Article 5.2 (g) of the delegated Regulation (EU) 2016/128) requires a mandatory statement with the description of properties and/or characteristics that make the products useful in relation to the disease, disorder or medical condition for the dietary management for which the product is intended. Thus, if a gluten-free labelling statement is relevant to the intended use of the FSMP and therefore appropriate to be included on the label, the conditions set out in the Annex of Regulation (EU) 828/2014 will apply.

Other Specialised Nutrition Products

Provided that the product meets the requirements established in Regulation (EU) 828/2014 and provided that the product also complies with the general conditions on fair information practices set out in Regulation (EU) No 1169/2011, the labels of the following products can inform consumers on the absence or reduced presence of gluten in a product:

- Complementary foods intended for infants or young children above 6 months of age;
- Slimming food (Total Diet Replacement & Meal Replacements for Weight Control);
- Sports food;
- and any other specialised nutrition products.

Gluten Statements and Labelling as Defined by the 'Gluten-Free' Regulation

Definitions of Statements

Gluten-Free (Annex A of Regulation (EU) 828/2014)

The statement 'gluten-free' may only be made where the food as sold to the final consumer contains no more than 20 mg/kg (= 20 ppm) of gluten.

Very Low Gluten (Annex A of Regulation (EU) 828/2014)

The statement 'very low gluten' may only be made where the food, consisting of or containing one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been specially processed to reduce the gluten content, contains no more than 100 mg/kg (=100 ppm) of gluten in the food as sold to the final consumer.

In addition to the elements of information highlighted above ("Gluten-Free" and "Very low in gluten"), these statements may be accompanied by the following statements:

- 'Suitable for people intolerant to gluten' or 'Suitable for coeliacs' (Article 3.2 of Regulation (EU) 828/2014)
- 'Specifically formulated for people intolerant to gluten' or 'Specifically formulated for coeliacs' (Article 3.3 of Regulation (EU) 828/2014) - if the food is specially produced, prepared and/or processed to:

> Reduce the gluten content of one or more gluten-containing ingredients; OR
> Substitute the gluten-containing ingredients with other ingredients naturally free of gluten.

SNE Recommendation

Food Business Operators should make sure that the statements 'Suitable for people intolerant to gluten', 'Suitable for coeliacs', 'Specifically formulated for people intolerant to gluten' or 'Specifically formulated for coeliacs' are only present on a label if the statements "Gluten-Free" or "Very low in gluten" are also present. It should, however, be noted that the claim 'Very low in gluten' is not suitable for coeliacs.



Information to Consumers About the Absence or Reduced Presence of Gluten in Food

On the basis of the EU Regulation, Specialised Nutrition Europe considers that **four categories** of food can be defined:

SNE Interpretation

CATEGORY 1: Cereal based food specially produced, prepared and or processed to meet the conditions of use of the statement 'Gluten-Free' or 'Very low gluten'



Without prejudice to national regulations including those covering special denominations and national interpretations to be confirmed by Food Business Operators before marketing the products, these types of food can state 'Gluten Free' or 'Very low gluten' and can voluntarily specify 'Suitable for people intolerant to gluten' or 'Suitable for coeliacs' AND / OR 'Specifically formulated for people intolerant to gluten' or 'Specifically formulated for coeliacs'. It should, however, be noted that the claim 'very low in gluten' is not suitable for coeliacs

The following products under the scope of Specialised Nutrition Europe can pertain to category 1 provided that the product meets the requirements established in Regulation (EU) 828/2014:

- Complementary foods intended for infants or young children above 6 months of age;
- Food for Special Medical Purposes (FSMPs);
- Slimming food (Total Diet Replacement & Meal Replacements for Weight Control);
- Sports food;
- Any other specialised nutrition product.

CATEGORY 2: Food that naturally and/or based on the manufacturing process does not contain gluten but that is part of a category of food that can contain gluten – and meets the requirements for gluten-free labelling

Without prejudice to national regulations including those covering special denominations and national interpretations to be confirmed by Food Business Operators before marketing

the products, these types of food can state ‘Gluten-Free’ and can voluntarily specify ‘Suitable for people intolerant to gluten’ or ‘Suitable for coeliacs’.

The following products under the scope of Specialised Nutrition Europe can pertain to Category 2 provided that the product meets the requirements established in Regulation (EU) 828/2014:

- Complementary foods intended for infants or young children above 6 months of age;
- Foods for Special Medical Purposes (FSMPs);
- Slimming food (Total Diet Replacement & Meal Replacements for Weight Control);
- Sports food;
- Any other specialised nutrition products.

SNE Recommendation

SNE recommends Food Business Operators to ascertain that they have information proving that other food among the category of food considered does (or could) contain gluten



SNE Interpretation

CATEGORY 3: Food that naturally does not contain gluten like any other food from the same category



Without prejudice to national regulations including those covering special denominations and national interpretations to be confirmed by Food Business Operators before marketing the products, these food are generally not authorised to bear a statement in relation to the absence or reduced presence of gluten, as article 7.1 of EU Regulation No 1169/2011 stipulates that food information shall not be misleading, particularly by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients.

CATEGORY 4: Food categories that are prohibited from informing on the absence or reduced presence of gluten in food



Without prejudice to national regulations including those covering special denominations and national interpretations to be confirmed by Food Business Operators before marketing the products, 'Gluten-Free' or 'Very low gluten' statements are strictly prohibited for **infant formula** and **follow-on formula**.

Compositional and information requirements related to infant formula and follow-on formula are set out in Regulation (EU) No 609/2013 supplemented by Delegated Regulation (EU) 2016/127 which stipulates that the use of ingredients containing gluten is not permitted in the production of infant formula and follow-on formula. Commission Implementing Regulation (EU) No 828/2014 (Article 4) specifically prohibits the provision of information on the absence or reduced presence of gluten in infant formula and follow-on formula.

Oat - A Specific Case

As specified in Recital 7 of Regulation (EU) 828/2014, most people with intolerance to gluten can include oats in their diet without adverse effect on their health.

Oats can be cross-contacted with wheat, which is a major concern. This can occur during grain harvesting, transport, storage and processing. Therefore, the risk of gluten cross-contact in products containing oats should be taken into consideration with regard to the relevant information provided by food business operators about those food products.

If oats are used, they need to have been specially produced, prepared and/or processed in a way to avoid cross-contact by wheat, rye, barley, or their crossbred varieties and the gluten content of such oats cannot exceed 20 mg/kg.

However, 5-10 % of coeliac patients show cross-reactivity to avenin (oats do not contain gluten per-se, avenin belongs to the same protein family). For this reason, coeliac patients' precaution is needed when it comes to eating processed oats and oats derivatives because there is an important likelihood of cross-contamination risks with them.

Food Business Operators' Responsibility: Risk Management & Communication

Article 17.1 of regulation (EC) 178/2002 (General Food Law) establishes that Food Business Operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met. Regulation (EC) 178/2002 on General Food Law also prohibits any practices, which may mislead the consumer.

Misleading claims on products are prohibited by the Food Information to Consumers Regulation (EC) 1169/2011, which states that food information must not be misleading, particularly in relation to the characteristics of the food; by attributing to the food effects or properties which it does not possess; or by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics.

The Nutrition and Health Claims Regulation (EC) 1924/2006 prohibits claims that are false, ambiguous or misleading; claims which give rise to doubt about the safety and/or the nutritional adequacy of other foods; and claims that encourage or condone excess consumption of a food.

Claims are defined in article 2.2 of this regulation as any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics.

As previously highlighted, Commission Regulation (EU) 828/2014 of 30 July 2014 establishes the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food. This is not a claim but information per se, as highlighted at the beginning of the recitals of Regulation (EU) 828/2014, which refers to the framework of Regulation (EU) No 1169/2011 on the provision of food information to consumers.

It is important that the information on gluten provided by any product placed on the EU market does not contravene any of the above legislation, and also that it is compliant with any other relevant EU laws.

How to Ensure Compliance?

Beyond the general requirements to be safe, applicable to all food (Regulation 178/2002 Article 14), there are actually no specific requirements in the EU Regulation on how to ensure compliance with the conditions of use for the information on the absence or reduced presence of gluten in food.

This falls under the responsibility of the Food Business Operator. The elements highlighted below are therefore linked to general hygiene and good manufacturing practice.

Regulation (EU) 828/2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food falls under the EU General Food Law, which means that the use of a “Gluten-Free” or “Very low in Gluten” statement is only possible if the necessary and appropriate elements are in place.

SNE Recommendation

It is recommended that manufacturers producing foods for people intolerant to gluten ensure that their facilities are either adequately cleaned down or dedicated to the production of such foods to eliminate any risk of cross-contact that could occur from multi-purpose food manufacturing.



If challenged, the food producer will need to demonstrate that they have put in place appropriate procedures and controls, in order to ensure that the final product does not contain more than the specified level of gluten. It is recommended that Food Business Operators show due diligence through their Critical Control Points, a system of record keeping and regular testing demonstrating consistent results.

Hazard Analysis Critical Control Point (HACCP)

Risk Analysis

As a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing, the Hazard Analysis and Critical Control Point (HACCP) should take into consideration the specific hazards linked to a gluten-free production line. This should therefore be integrated in the hazard analysis that is used as a premise to the establishment of the HACCP system, under the responsibility of the FBO.

Specific control points

FBO shall include gluten control in the HACCP plan for processing as a critical control point. Relying on the statements of the suppliers in ingredient specifications is not sufficient.

FBO will need to ensure verification of legal compliance by analytical control. The extent of these controls will depend on the production environment (e.g. the risk of cross contact) and the level of assurance given by the suppliers of the raw materials.

If the products are produced in an environment where wheat-containing products are produced, stored or used, cross-contact is almost impossible to avoid. Quality assurance measures should be in place (in the context of the HACCP plan) to avoid such cross-contact.

In addition, verification should be carried out on an appropriate number of samples of every batch of the final product. If manufacturing is taking place in an environment where no wheat-containing ingredients are used, the risks are easier to manage and appropriate sampling of the raw materials and/ or final products will be required, as relevant.

Tests

Food Business Operators shall apply an appropriate testing system to ensure that the critical control point is adequately controlled.

Given that Regulation (EU) No 828/2014 specifically refers to the Codex Standard 118-1979, the provisions on analysis and sampling in that standard can be considered, e.g. the Enzyme-linked Immunoassay (ELISA) R5 Mendez Method.

METHODS OF ANALYSIS AND SAMPLING

Codex Standard 118-1979 - STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN, provides for the following elements regarding methods of analysis and sampling that can be applied by Food Business Operators without prejudice to any national regulations and interpretations to be confirmed by Food Business Operators before marketing the products. Food Business Operators are responsible for establishing methods of analysis and sampling that are compliant with the requirements linked to the country where the food is marketed General outline of the methods (Section 5.1)

- *The quantitative determination of gluten in foods and ingredients shall be based on an immunologic method or other method providing at least equal sensitivity and specificity.*
- *The antibody used should react with the cereal protein fractions that are toxic for persons intolerant to gluten and should not cross-react with other cereal proteins or other constituents of the foods or ingredients.*
- *Methods used for determination should be validated and calibrated against a certified reference material, if available.*
- *The detection limit has to be appropriate according to the state of the art and the technical standard. It should be 10 mg gluten/kg or below.*
- *The qualitative analysis that indicates the presence of gluten shall be based on relevant methods (e.g. ELISA-based methods, DNA methods)*

Wheat Labelling as Allergen in a Gluten-Free Product

Wheat is one of the 14 major allergens defined in Annex II to Regulation No 1169/2011 on the provision of food information to consumers. Any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form, must be listed on the label.

It is therefore possible to use wheat in a commodity and indicate its presence in the list of ingredients and to mention the statement "gluten-free" on the label, when the gluten level is lower than 20 mg/kg.

SNE Interpretation

To date, the mention "very low gluten" is used very little by Food Business Operators to the extent that the tolerance to gluten in individuals is difficult to quantify. Coeliac disease is scientifically unquantifiable (between 20 and 100mg/kg).



Position on the Label

SNE Recommendation

If a Food Business Operator chooses not to place this statement on the front of pack (FOP), it would be best practice for this information to be placed with the ingredients list and/or any allergen information.



When the legal name of the product appears in FOP, SNE recommends for the gluten information to appear in the vicinity of the legal name.

Use of Gluten-Free Logos and Symbols

SNE Interpretation

Without prejudice to national regulations including those covering special denominations and national interpretations to be confirmed by Food Business Operators before marketing the products, SNE considers that FBO are not prohibited from using a logo/symbol in conjunction with the statements "gluten-free", to reinforce the suitability of products for this particular group of consumers.



If using a logo/symbol, it must however be clear that this has the same meaning as the statement "gluten-free".

The use of logos or symbols to inform consumers about the absence or reduced presence of gluten in a food is not specifically addressed in Commission Implementing Regulation (EU) No 828/2014. The voluntary use of any such logos or symbols must meet the general requirements established in Regulation (EU) No 1169/2011 as explained above.

All products carrying such a logo/symbol must therefore meet the relevant compositional and labelling requirements and comply with the EU Regulation.

Such logo/symbol cannot be used on its own.

Certain third-party certification/auditing bodies have established specific logos that FBO can use on the package of their products after being audited. One example for such a logo is the Crossed Grain Trademark.

Notification

The EU Food Regulation does not require gluten-free food to be notified at national level.

SNE Recommendation

Food Business Operators are encouraged to contact national authorities, national specialised nutrition industry associations or national coeliacs societies in order to assess the situation within a specific market.



Terminology

FIC	Food Information to Consumers Regulation (EU) 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers
FBO	Food Business Operator
MS	EU Member States
NHCR	Nutrition and Health Claims Regulation Regulation (EC) 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods
SNE	Specialised Nutrition Europe

For further information, please contact:



Avenue des Nerviens 9-31, 1040 Brussels, Belgium
Tel: +32 2 508 10 74 s@specialisednutritioneurope.eu
www.specialisednutritioneurope.eu



EU Transparency Register: 33498019160-40