

SNE | GUIDANCE ON GLUTEN FREE LABELLING

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1 INTRODUCTION

Warning

Context

WARNING

This guidance document is intended to provide SNE members and Food Business Operators with information on the EU regulatory changes to **Gluten Free and Low in Gluten** legislation and is for general information purposes only. The information contained herein does not constitute legal or other professional advice. No member of SNE accepts any responsibility or liability to users or any third parties in relation to the use of the information contained in this guidance.

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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

The new Commission 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to consumers on the absence or reduced presence of gluten in food has entered into force on 20 July 2016 and has repealed regulation (EC) 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten.

This enters in the more general context of repeal of the PARNUTS Directives and reflects a new horizontal approach for gluten free food in line with Regulation (EU) 1169/2011 (Article 36.3). However, 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 has specific requirements for statements related to gluten.

2 SCOPE AND DEFINITIONS

Definitions

Scope

Relevant legislation

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 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

SNE interprets coeliac disease as an autoimmune condition where the consumption of gluten triggers the immune system to react and damage the lining of the small intestine, causing intestinal malabsorption. According to recital 1, people with coeliac disease suffer from a permanent intolerance to gluten.

The malabsorption syndrome is precipitated by the ingestion of foods containing gluten, such as wheat, rye, and barley. It is characterized by inflammation of the small intestine, loss of microvilli structure, failed intestinal absorption, and malnutrition.¹

SNE
Interpretation

SCOPE

With the repeal of the PARNUTs framework, the previous distinction for Gluten-free foods between Food for a particular nutritional use (PARNUTs) and general food no longer exists.

¹ “coeliac disease”[MeSH Terms], <https://www.ncbi.nlm.nih.gov/mesh/?term=coeliac+disease>

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 and where appropriate;
- they shall be based on the relevant scientific data.

Allergen Labelling

As stipulated in article 9.1 (c), the indication of any ingredient (...), even if in an altered form, is **mandatory**.

Annex II of Regulation (EU) No 1169/2011 lists the substances or products containing gluten as causing allergies or intolerances (e.g. cereals containing gluten).

Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridised strains, and products thereof, except: (a) wheat based glucose syrups including dextrose²; (b) wheat based maltodextrins³; (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 Regulation No 828/2014.

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 – Directive 2006/141/EC

Compositional and information requirements related to infant formula and follow-on formula are set out in Directive 2006/141/EC (and Annex I and II of the delegated regulation (EU) No. 2017/127) 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 – Directive 1999/21/EC

² 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.

³ Idem.

Article 4.4 (c) of Commission Directive 1999/21/EC on dietary foods for special medical purposes (and Article 5.2 (g) of the delegated Regulation (EU) No. 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 include on the label, the conditions set out in the Annex of Regulation (EU) 828/2014 will apply.

Other Specialised Nutrition Products

Complementary foods above 6 months, Slimming food (Total Diet Replacement and Meal replacements for weight control), sports food and any other specialised nutrition product can inform consumers on the absence or reduced presence of gluten in a product, provided that this 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.

3 GLUTEN STATEMENTS AND LABELLING AS DEFINED BY REGULATION EU 828/2014

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GLUTEN STATEMENTS AND LABELLING AS DEFINED BY REGULATION EU 828/2014

STATEMENT DEFINITIONS

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 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 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

FBOs have to be careful 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.

SNE
recommendation

FOOD AUTHORISED (OR NOT) TO INFORM CONSUMERS ON THE ABSENCE OR REDUCED PRESENCE OF GLUTEN IN FOOD

SNE interpretation

On the basis of the EU Regulation, SNE considers that four categories of food can be defined:

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 of 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'.

Under SNE scope of products, Complementary food, FSMPs, Slimming food (Total Diet Replacement and Meal replacements for weight control), sports food and any other specialised nutrition product can pertain to category 1 provided that the product meets the requirements established in Regulation (EU) 828/2014.

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 of 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'.

Under SNE scope of products, Complementary food, FSMPs, Slimming food (Total Diet Replacement and Meal replacements for weight control), sports food and any other specialised nutrition product can pertain to category 2 provided that the product meets the requirements established in Regulation (EU) 828/2014.

SNE
Interpretation

SNE recommendation

SNE recommends Food Business Operators to keep information internally proving that other food among the category of food considered contains gluten.

SNE
recommendation

SNE interpretation

SNE
Interpretation

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

Without prejudice of 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 of 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:

- > Compositional and information requirements related to infant formula and follow-on formula are set out in Directive 2006/141/EC 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*

A SPECIFIC CASE - OAT

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.

However, a major concern is the contamination of oats with wheat, rye or barley that can occur during grain harvesting, transport, storage and processing. Therefore, the risk of gluten contamination in products containing oats should be taken into consideration with regard to the relevant information provided on those food products by food business operators.

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

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 the new 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

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-contamination that could occur from multi-purpose food manufacturing.

If challenged, the food producer will need to demonstrate that they had 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.

Showing due diligence through Critical Control Points, a system of record keeping and regular testing to demonstrate consistent results is advisable.

- 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 in which also wheat containing products are produced, stored or used, the risks of cross contamination are 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

FBO 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.

WHEAT ALLERGY VS. COELIAC DISEASE

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.

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. When wheat is used in a commodity, it must be emphasized in the lists of ingredients, in compliance with the FIC Regulation.

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).

SNE
Interpretation

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.

SNE
recommendation

USE OF GLUTEN FREE LOGOS AND SYMBOLS

SNE interpretation

Without prejudice of 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.

SNE
Interpretation

NOTIFICATION

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

SNE recommendation

FBO are invited to contact national authorities or national associations in order to assess the situation within a specific market.

SNE
recommendation

4 TERMINOLOGY

TERMINOLGY

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

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