



Food Safety
AUTHORITY OF IRELAND

24

GUIDANCE NOTE

**‘Gluten-free’ and
‘Very Low Gluten’ Declarations
(Revision 2)**

**Guidance Note No. 24
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'Very Low Gluten' Declarations
(Revision 2)**

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I. INTRODUCTION

The use of cereals containing gluten in the production of prepacked and non-prepacked food must be declared in accordance with Regulation (EU) No 1169/2011 governing the provision of food information to consumers (FIC). However, the provision of statements declaring the absence or low level presence of gluten in food (prepacked or non-prepacked) is at the discretion of the food business. The provision of such voluntary statements must be in line with the requirements set out in Commission Implementing Regulation (EU) No 828/2014. Information relating to the presence, absence or low level presence of gluten in food is important for people with coeliac disease, people with non-coeliac gluten sensitivity, and for those who decide to switch to a gluten-free diet. Therefore, it is essential that such information is accurate so that it does not mislead or endanger the health of vulnerable consumers.

Commission Implementing Regulation (EU) No 828/2014 on the 'Information to Consumers on the Absence or Reduced Presence of Gluten in Food' defines 'gluten' as a protein fraction from wheat (all *Triticum* species), 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.

2. SCOPE

This guidance document deals with EU legislation governing voluntary information statements provided to consumers about the absence or reduced presence of gluten in food. The relevant EU legislation (Commission Implementing Regulation (EU) No 828/2014) came into effect on July 20th, 2016 and is designed to ensure the consistency and reliability of statements declaring the absence or reduced presence of gluten in food sold to the final consumer. This guidance is aimed at environmental health officers (EHOs) in the Health Service Executive (HSE) and can also be of interest to food businesses.

3. RELEVANT LEGISLATION

3.1 Regulation (EU) No 1169/2011 on the Provision of Food Information to Consumers (FIC)

Regulation (EU) No 1169/2011 (S.I. No. 565 of 2014) on the provision of food information to consumers (FIC) establishes the general principles, requirements and responsibilities governing food information and is applicable to the labelling and advertising of food. With the exception of specified derivatives, cereals containing gluten, namely: wheat (such as spelt and khorasan wheat), rye, barley, oats, or their hybridised strains and products thereof must be highlighted in the list of ingredients in accordance with the requirements of Regulation (EU) No 1169/2011. The requirement for mandatory indication applies even where the final food carries either of the statements outlined in Sections 4.1 ('Gluten-free') and 4.2 ('Very low gluten'). Voluntary declarations such as 'Gluten-free' or 'Very low gluten' may only be provided if they are in accordance with Article 36.2 of Regulation (EU) No 1169/2011 which stipulates that they shall not mislead the consumer, shall not be ambiguous or confusing and where appropriate, shall be based on the relevant scientific data.

3.2 Commission Implementing Regulation (EU) No 828/2014 on Information to Consumers on the Absence or Reduced Presence of Gluten in Food

Commission Implementing Regulation (EU) No 828/2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food came into effect on July 20th, 2016. This Regulation is designed to ensure that voluntary information relating to the absence or reduced presence of gluten in food is in accordance with Article 36(2) of Regulation (EU) No 1169/2011. Article 4 of Commission Implementing Regulation (EU) No 828/2014 specifically prohibits the provision of information on the absence or reduced presence of gluten in infant formulae and follow-on formulae.

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

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. These requirements will be updated through delegated acts foreseen in Article 11.1 of Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. The mandatory provision of information regarding cereals containing gluten is set out in Regulation (EU) No 1169/2011 and applies to food including cereal-based foods and baby foods for infants and young children. 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.

3.4 Directive 2006/141/EC and Commission Delegated Regulation (EU) 2016/127 on Infant Formula and Follow-on Formula

Compositional and information requirements related to infant formula and follow-on formula are set out in Directive 2006/141/EC and Commission Delegated Regulation (EU) 2016/127 which stipulate that the use of ingredients containing gluten is not permitted in the production of infant formula and follow-on formula. Article 4 of Commission Implementing Regulation (EU) No 828/2014 specifically prohibits the provision of information on the absence or reduced presence of gluten in infant formulae and follow-on formulae.

Article 13 of Commission Delegated Regulation (EU) 2016/127 indicates that Directive 2006/141/EC is repealed with effect from 22 February 2020, however, it shall continue to apply until 21 February 2022 to infant formula and follow-on formula manufactured from protein hydrolysates.

4. PERMITTED STATEMENTS ON THE ABSENCE OR REDUCED PRESENCE OF GLUTEN IN FOOD

Where a food business decides to voluntarily provide statements to inform consumers about the absence or reduced presence of gluten in a prepackaged or non-prepackaged food, only the following wording is permitted in accordance with Commission Implementing Regulation (EU) No 828/2014;

4.1 'Gluten-free'

The statement 'gluten-free' may only be used in the labelling or advertising of a food sold to the final consumer which contains no more than 20 mg/kg (or parts per million, ppm) of gluten.

4.2 'Very low gluten'

The statement 'very low gluten' may only be used where 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 to no more than 100 mg/kg (ppm) of gluten in the food as sold to the final consumer.

4.3 Additional Permitted Statements

- a) The statements outlined in Sections 4.1 and 4.2 may be accompanied by the following statements; *“suitable for people intolerant to gluten”* and *“suitable for coeliacs”*

Note: *These additional statements may not be used instead of the statements in Sections 4.1 and 4.2*

- b) The statements outlined in Sections 4.1 and 4.2 may be accompanied by the following statements; *“specifically formulated for people intolerant to gluten”* or *“specifically formulated for coeliacs”* as long as the food is specifically 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

Note: *These additional statements may not be used instead of the statements set out in Sections 4.1 and 4.2.*

- c) The statements outlined in Sections 4.1 and 4.2 may be used in relation to a food containing oats, only where the oats has been specifically produced, prepared and/or processed in a way to avoid contamination by wheat, rye, barley or their crossbred varieties, and the gluten content of the oats does not exceed 20 mg/kg (ppm).

5. USE OF LOGOS OR SYMBOLS

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. However, the voluntary use of any such logos or symbols must not mislead consumers in accordance with Article 7 and Article 36.2 of Regulation (EU) No 1169/2011.

6. FOOD THAT IS NATURALLY GLUTEN-FREE

The provision of information indicating the absence of gluten in foods that naturally do not contain gluten is permitted only where that information does not mislead consumers in accordance with the requirement for fair information practices set out in Article 7 of Regulation (EU) No 1169/2011. In particular, food information should not be misleading by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics. For single ingredient foods, it should be easy to determine whether such information would be misleading or not, e.g. putting a 'gluten-free' statement on a milk carton could be considered misleading as it associates a special characteristic with that particular milk, when in fact, all milk is gluten-free. However, it may be more complicated for foods containing a number of ingredients which would need to be assessed on a case-by-case basis.

7. GLUTEN ANALYSIS

A variety of laboratories and analytical methods are available for determining the presence and relative content of gluten in food. Food businesses should ensure that the laboratory they choose to determine the gluten content in their final product is accredited and that the test method used is of an international standard and meets the regulatory requirements in the country where the food is to be marketed.

8. CROSS-CONTAMINATION

Cross-contamination of foods with gluten-containing cereals is a constant risk during the production, transport, processing and preparation of all food and should be managed as part of a HACCP plan. Food businesses using voluntary statements such as 'gluten-free' or 'very low gluten' on products for sale to the final consumer are entirely responsible for the accuracy of such claims.

9. POSITIONING OF VOLUNTARY INFORMATION ON LABELS

Voluntary food information cannot be displayed to the detriment of the space available for mandatory food information (Article 37 of Regulation (EU) No 1169/2011).




10. CONCLUSION

Food businesses may choose to indicate that their food is suitable for people with coeliac disease, people with non-coeliac gluten sensitivity, and for those who decide to switch to a gluten-free diet. However, statements providing such information can only be used on food labels or associated advertising or other material if they adhere to the specific wording outlined in Commission Implementing Regulation (EU) No 828/2014. In addition, food businesses must ensure that any form of voluntary information about the absence or reduced presence of gluten in a food adheres to the requirement for fair information practices set out in Article 36.2 of Regulation (EU) No 1169/2011.



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