

Working Document prepared by the Commission services - does not prejudice the Commission's final decision
11/11/2013

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COMMISSION IMPLEMENTING REGULATION (EU) No .../..

of XXX

on the requirements for the provision of food information on the absence or reduced presence of gluten in food

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers¹, and in particular Article 36(3)(d) thereof,

Whereas:

- (1) People with coeliac disease suffer from a permanent intolerance to gluten. 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 coeliac people and therefore it should be avoided by them.
- (2) Information on the absence or reduced presence of gluten in foods should help coeliac people identify and choose a varied diet at home or outside. The food industry has developed a range of products presented as 'gluten-free' or with similar equivalent terms.
- (3) Commission Regulation (EC) No 41/2009² sets out harmonised rules on the information that is provided to consumers on the absence ("gluten-free") or reduced presence of gluten ("very low gluten") in food. Regulation (EU) No 609/2013³ of the European Parliament and the Council foresees the repeal of Regulation (EC) No 41/2009 from 20 July 2016.
- (4) Consumers should continue to be appropriately informed and not misled or confused when information on the absence or reduced presence of gluten in foods is provided by food business operators after the repeal of Regulation (EC) No 41/2009. It is therefore necessary to establish uniform conditions for food information provided by food business operators on the absence or reduced presence of gluten in food.

¹ OJ L 304 , 22.11.2011, p.18

² Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten, OJ L 16, 21.1.2009, p. 3

³ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009, OJ L 181, 29.6.2013, p. 35

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- (5) Certain foods have been specially produced, prepared and/or processed to reduce the gluten content of one or more gluten containing ingredients or to substitute the gluten containing ingredients with other ingredients naturally free of gluten. Other foods are made exclusively from ingredients that are naturally free of gluten.
- (6) The removal of gluten from gluten-containing grains presents considerable technical difficulties and economic constraints and therefore the manufacture of totally gluten-free food when using such grains is difficult. Consequently, many foods especially processed to reduce the gluten content of one or more gluten containing ingredients on the market may contain low residual amounts of gluten.
- (7) Most but not all people with intolerance to gluten can include oats in their diet without adverse effect on their health. This is an issue of ongoing study and investigation by the scientific community. 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.
- (8) Different people with intolerance to gluten may tolerate variable small amounts of gluten within a restricted range. In order to enable individuals to find on the market a variety of foodstuffs appropriate for their needs and for their level of sensitivity, a choice of products should be possible with different low levels of gluten within such a restricted range. It is important, however, that the different products should be properly labelled in order to ensure the correct use of those products by people intolerant to gluten with the support of information campaigns fostered in the Member States.
- (9) It should be possible for foods which are specially produced, prepared and/or processed to reduce the gluten content of one or more gluten containing ingredients or to substitute the gluten containing ingredients with other ingredients naturally free of gluten to bear terms indicating the absence ("gluten-free") or reduced presence ("very low gluten") of gluten. It should also be possible for these products to inform consumers that they are specifically formulated for people intolerant to gluten.
- (10) It should also be possible for a food containing ingredients naturally free of gluten to bear terms indicating the absence of gluten, provided that the general conditions on fair information practices are complied with. In particular, account should be taken of the requirement of Regulation (EU) No 1169/2011 of the European Parliament and the Council whereby food information should not be misleading by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics.
- (11) Commission Directive 2006/141/EC⁴ prohibits the use of ingredients containing gluten in the manufacture of infant formulae and follow-on formulae. Therefore, the use of the terms "very low gluten" or "gluten-free" when providing information on such products should be prohibited given that pursuant to the present Regulation, these

⁴ Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC, OJ L 401, 30.12.2006, p. 1

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terms are used for indicating respectively a content of gluten not exceeding 100 mg/kg and 20 mg/kg.

- (12) Commission Directive 2006/125/EC⁵ requires the indication of the presence or the absence of gluten when processed cereal-based foods and baby foods are intended for infants below six months of age. The absence of gluten in those products should be indicated in accordance with the requirements laid down in this Regulation.
- (13) The Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten was adopted by the 31st session of the Codex Alimentarius Commission in July 2008⁶, with a view to enabling those persons to find on the market a variety of food suitable to their needs and to their level of sensitivity to gluten. That standard should be taken appropriately into consideration for the purposes of this Regulation.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1 *Scope*

1. The provision of food information on the absence or reduced presence of gluten in foods shall be permitted only if it complies with this Regulation.
2. The provision of food information on the absence or reduced presence of gluten in infant formulae and follow-on formulae as defined in Directive 2006/141/EC shall be prohibited.

Article 2 *Definitions*

For the purposes of this Regulation, the following definitions shall apply:

- (a) "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;
- (b) "wheat" means any *Triticum* species.

⁵ Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children, OJ L 339, 6.12.2006, p. 16

⁶ http://www.codexalimentarius.net/download/standards/291/cxs_118e.pdf

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Article 3
Information to consumers

1. Statements on the absence or reduced presence of gluten in the labelling, advertising and presentation of foods shall only be permitted if they are listed in the Annex to this Regulation and are in conformity with the conditions of use set out therein.
2. When information is provided to consumers on the absence or reduced presence of gluten in the labelling, advertising and presentation of foods in accordance with paragraph 1, such information shall appear in proximity to the name under which the food is sold.
3. When information is provided to consumers on the absence or reduced presence of gluten in the labelling, advertising and presentation of foods in accordance with paragraph 1, such information may be accompanied by the statements "suitable for coeliacs" or "suitable for people intolerant to gluten" or any statement likely to have the same meaning for the consumer.
4. When information is provided to consumers on the absence or reduced presence of gluten in the labelling, advertising and presentation of foods which are specially produced, prepared and/or processed to meet the conditions set out in Annex, such information may be accompanied by the statement "specifically formulated for people intolerant to gluten".

Article 4
Entry into force and application

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 20 July 2016.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
[\[...\]](#)

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Annex

Statements on the absence or reduced presence of gluten in the labelling, advertising and presentation of foods that are allowed to be made and conditions thereof

A. General requirements

GLUTEN-FREE

A statement that a food is gluten-free, and any statement likely to have the same meaning for the consumer, 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

A statement that a food is very low in gluten, and any statement likely to have the same meaning for the consumer, 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.

B. Additional requirements for foods containing oats

Oats contained in food presented as gluten-free or very low gluten must 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.