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

**of **XXX****

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

(Text with EEA relevance)

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

of **XXX**

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

(Text with EEA relevance)

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 of 25 October 2011 on the provision of food information to consumers<sup>1</sup>, 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 people intolerant to gluten and therefore its consumption should be avoided by such people.
- (2) Information on the absence or reduced presence of gluten in food should help people intolerant to gluten to identify and choose a varied diet when eating inside or outside the home.
- (3) Commission Regulation (EC) No 41/2009<sup>2</sup> sets out harmonised rules on the information provided to consumers on the absence ("gluten-free") or reduced presence of gluten ("very low gluten") in food. The rules of that Regulation are based on scientific data and guarantee that consumers are not misled or confused by information provided on a divergent basis on the absence or reduced presence of gluten in food.
- (4) In the context of the revision of the legislation on foodstuffs intended for particular nutritional uses Regulation (EU) No 609/2013 of the European Parliament and of the Council<sup>3</sup> repeals Regulation (EC) No 41/2009 from 20 July 2016. It should be ensured that, after that date, the provision of information on the absence or reduced presence of gluten in food continues to be based on the relevant scientific data and is not provided on a divergent basis which could mislead or confuse the consumers, in accordance with the requirements laid down in Article 36(2) of Regulation (EU) No 1169/2011. It

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<sup>1</sup> OJ L 304 , 22.11.2011, p. 18.

<sup>2</sup> 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).

<sup>3</sup> 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).

is therefore necessary that uniform conditions for the application of these requirements to food information provided by food business operators on the absence or reduced presence of gluten in food are maintained in the Union and these conditions should be based on Regulation (EC) No 41/2009.

- (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 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 are properly labelled in order to ensure their correct use by people intolerant to gluten with the support of information campaigns fostered in the Member States.
- (9) It should be possible for a food which is 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 either the absence ("gluten-free") or reduced presence ("very low gluten") of gluten in accordance with the provisions laid down in this Regulation. It should also be possible for this food to bear a statement informing consumers that it is 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 set out in Regulation (EU) No 1169/2011 are complied with. 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.
- (11) Commission Directive 2006/141/EC<sup>4</sup> prohibits the use of ingredients containing gluten in the manufacture of infant formulae and follow-on formulae. Therefore, the use of the statements "very low gluten" or "gluten-free" when providing information on such products should be prohibited given that pursuant to the present Regulation, these

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<sup>4</sup> 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).

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

- (12) The Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten<sup>5</sup> should be taken appropriately into consideration for the purposes of this Regulation.
- (13) 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 and subject matter***

This Regulation applies to the provision of information to consumers on the absence or reduced presence of gluten in food.

*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.

*Article 3*  
***Information to consumers***

1. Where information is provided to consumers on the absence or reduced presence of gluten in food, such information shall be given only through the statements and in accordance with the conditions set out in the Annex.
2. The food information referred to in paragraph 1 may be accompanied by the statement "suitable for people intolerant to gluten".
3. The food information referred to in paragraph 1 may be accompanied by the statement "specifically formulated for people intolerant to gluten" if the food is specially produced, prepared and/or processed to:
  - (a) reduce the gluten content of one or more gluten containing ingredients or;
  - (b) substitute the gluten containing ingredients with other ingredients naturally free of gluten.

*Article 4*  
***Infant formulae and follow-on formulae***

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.

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<sup>5</sup> [http://www.codexalimentarius.net/download/standards/291/cxs\\_118e.pdf](http://www.codexalimentarius.net/download/standards/291/cxs_118e.pdf).

*Article 5*  
***Entry into force and application***

This Regulation shall enter into force on the twentieth 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*  
*José Manuel BARROSO*