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Subject: COMMISSION DELEGATED REGULATION (EU) No .../. of 21.8.2013  
amending Regulation (EU) No 1169/2011 of the European Parliament and of  
the Council on the provision of food information to consumers as regards  
information on the absence or reduced presence of gluten in food

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Delegations will find attached Commission document C(2013) 5405final.

Encl.: C(2013) 5405 final.



Brussels, 21.8.2013  
C(2013) 5405 final

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

**of 21.8.2013**

**amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council  
on the provision of food information to consumers as regards information on the  
absence or reduced presence of gluten in food**

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE DELEGATED ACT

Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten<sup>1</sup> sets out harmonised rules on the information that is provided to consumers on the absence or reduced presence of gluten in food. More specifically, the Regulation sets out harmonised rules on the use of the statements 'gluten-free' and 'very low gluten'. That Regulation was adopted under Directive 2009/39/EC<sup>2</sup> which establishes the legislative framework for foodstuffs for particular nutritional uses, so-called 'dietetic foods'.

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>3</sup> sets out rules on information to be provided for all food, including non prepacked food, on the presence of ingredients, such as gluten-containing ingredients, with a scientifically proven allergenic or intolerance effect in order to enable consumers, particularly those suffering from a food allergy or intolerance such as gluten intolerant people, to make informed choices which are safe for them.

Directive 2009/39/EC and Regulation (EC) No 41/2009 will be repealed by Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special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<sup>4</sup>. Nevertheless, 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. To this end, it is necessary to transfer the existing rules under a different legal framework. In this context, Regulation (EU) No 609/2013 foresees that for the sake of clarity and consistency, the rules on the use of the statements 'gluten-free' and 'very low gluten' should be regulated under Regulation (EU) No 1169/2011.

Article 36(2) of Regulation (EU) No 1169/2011 requires that information provided by food business operators shall not mislead the consumer, shall not be ambiguous or confusing for the consumer and shall, where appropriate, be based on the relevant scientific data. To that effect, Article 36(3) of that Regulation requires the Commission to adopt implementing acts on the application of the requirements referred to in paragraph 2 of the same Article in certain specific cases identified therein.

In order to ensure that consumers are appropriately informed and not misled or confused by information provided by food business operators on a divergent basis, Article 36(4) of that Regulation provides for the possibility for the Commission to supplement, by means of delegated acts, Article 36(3) with additional cases of provision of food information for which the Commission shall adopt implementing acts on the application of the requirements referred to in Article 36(2).

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<sup>1</sup> OJ L 16, 21.1.2009, p. 3.

<sup>2</sup> OJ L 124, 20.5.2009, p. 21.

<sup>3</sup> OJ L 304, 22.11.2011, p. 18.

<sup>4</sup> OJ L 181, 29.6.2013, p. 35.

This Delegated Regulation amends Article 36(3) of Regulation (EU) No 1169/2011 by supplementing it with the addition of a new letter (d): 'information on the absence or reduced presence of gluten in food'.

Following its adoption, the Commission intends to prepare an implementing act on the basis of amended Article 36(3) of Regulation (EU) No 1169/2011 in order to transfer the rules of Commission Regulation (EU) No 41/2009 under the new legislative framework of Regulation (EU) No 1169/2011.

## **2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT**

The Expert Group on Regulation (EU) No 1169/2011 on the provision of food information to consumers was consulted on the subject of this draft Commission Regulation. The consultation took place at the Expert Group's meeting of 24 May 2013 on the basis of a Working Document prepared by the Commission services. Experts supported the approach described by the Commission in that Working Document.

## **3. LEGAL ELEMENTS OF THE DELEGATED ACT**

The legal basis for this Delegated Regulation is Article 36(4) of Regulation (EU) No 1169/2011 on the provision of food information to consumers.

This Delegated Regulation amends Article 36(3) of Regulation (EU) No 1169/2011 by supplementing it with the addition of a new letter (d): 'information on the absence or reduced presence of gluten in food'.

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

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**amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council  
on the provision of food information to consumers as regards 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 of 25 October 2011 on the provision of food information to consumers<sup>5</sup>, and in particular Article 36(4) thereof,

Whereas:

- (1) Paragraph 2 of Article 36 of Regulation (EU) No 1169/2011 requires that information that may be provided by food business operators does not mislead the consumer, is not ambiguous or confusing for the consumer and, where appropriate, is based on the relevant scientific data.
- (2) According to paragraph 3 of that Article the Commission is to adopt implementing acts on the application of those requirements to the cases identified in that paragraph.
- (3) Paragraph 4 of that Article provides for the possibility to supplement paragraph 3 by adding other specific cases in which the Commission is to implement those requirements in order to ensure that consumers are appropriately informed.
- (4) People with coeliac disease suffer from a permanent intolerance to gluten. Gluten can cause adverse effects to those people and therefore it should be absent or present in very low amounts in their diet.
- (5) Regulation (EC) No 41/2009<sup>6</sup> sets out harmonised rules on the information that is provided to consumers on the absence or reduced presence of gluten in food. Regulation (EU) No 609/2013<sup>7</sup> foresees the repeal of Regulation (EC) No 41/2009 from 20 July 2016.

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<sup>5</sup> OJ L 304, 22.11.2011, p.18.

<sup>6</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>7</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

- (6) 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 amend paragraph 3 of Article 36 of Regulation (EU) No 1169/2011 in order to allow the Commission to establish uniform conditions for food information on the absence or reduced presence of gluten in food that may be provided by food business operators,

HAS ADOPTED THIS REGULATION:

*Article 1*

In the first subparagraph of Article 36(3) of Regulation (EU) No 1169/2011, the following point (d) is added:

"(d) information on the absence or reduced presence of gluten in food."

*Article 2*

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

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

Done at Brussels, 21.8.2013

*For the Commission*  
*The President*  
*José Manuel BARROSO*