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COMMISSION

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COMMISSION REGULATION (EU) .../...

of **XXX**

**amending Annexes II and III to Regulation (EC) No 1333/2008 of the European
Parliament and of the Council as regards foods intended for particular nutritional uses**

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards foods intended for particular nutritional uses

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives¹, and in particular Article 10(3) thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings², and in particular Article 7(5) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food and their conditions of use. Part E of Annex II to Regulation (EC) No 1333/2008 includes, among others, food category 13 ‘Foods intended for particular nutritional uses as defined by Directive 2009/39/EC’.
- (2) Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives including carriers approved for use in food additives, food enzymes, food flavourings, nutrients and their conditions of use.
- (3) Certain food categories, subcategories, provisions and conditions of use in Part E of Annex II to Regulation (EC) No 1333/2008 refer to Directive 2009/39/EC of the European Parliament and of the Council³, which covered foods intended for particular nutritional uses, and to some Commission Directives on such foods. Since those Directives were repealed by Regulation (EU) No 609/2013 of the European Parliament and of the Council⁴, those references should be updated
- (4) As food category 13 refers to Directive 2009/39/EC, the reference should be replaced by a reference to Regulation (EU) No 609/2013.

¹ OJ L 354, 31.12.2008, p. 16, ELI: <http://data.europa.eu/eli/reg/2008/1333/oj>.

² OJ L 354, 31.12.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/1331/oj>.

³ Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (OJ L 124, 20.5.2009, p. 21, ELI: <http://data.europa.eu/eli/dir/2009/39/oj>).

⁴ 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, ELI: <http://data.europa.eu/eli/reg/2013/609/oj>).

- (5) As food categories 13.1.1 and 13.1.2 refer to Directive 2006/141/EC and this Directive was repealed by Regulation (EU) No 609/2013, the reference should be replaced by a reference to that Regulation.
- (6) As footnotes 15, 43 and 44 to food categories 13.1.1 and 13.1.2 include references to repealed Directives, the references should be updated.
- (7) Food category 13.1.3 refers to processed cereal-based foods and baby foods for infants and young children as defined by Commission Directive 2006/125/EC⁵. These products are now defined by Regulation (EU) No 609/2013 and therefore the reference should be replaced.
- (8) Food category 13.1.4 covers other foods for young children, namely milk-based products for young children other than foods mentioned in the other subcategories under food category 13. As these products are not within the scope of Regulation (EU) No 609/2013, it is appropriate to delete that category 13.1.4 and to create, only for the purposes of the Union food additives legislation, a new subcategory 01.10 of the food category 01. 'Dairy products and analogues' for those products. The list of food additives authorised for use and their conditions of use should however not be affected, and only references which appear irrelevant should be deleted.
- (9) As food categories 13.1.5 and 13.2 and subcategory 13.1.5.2 refer to Directive 1999/21/EC and this Directive was repealed by Regulation (EU) No 609/2013, the references should be replaced by references to that Regulation. Furthermore, as food category 13.1.5 and subcategory 13.1.5.1 refer to 'special formulae for infants' and that concept is not used under Regulation (EU) No 609/2013, that expression should be deleted.
- (10) Food category 13.3 covers dietary foods for weight control diets intended to replace the total daily food intake or an individual meal (the whole or part of the total daily diet). As Regulation (EU) No 609/2013 covers only total diet replacement for weight control, references to food category 13.3 should be amended accordingly and foods substituting one or two of the main daily meals of an energy restricted diet, with meal replacements contributing to weight loss or the maintenance of weight after weight loss. should be moved to food category 18 as a new subcategory 18.2. Since the requirements on the composition of these foods allowed to bear the corresponding health claim are laid down in Commission Regulation (EU) No 432/2012⁶, the title of this new subcategory should refer to that Regulation.
- (11) Food category 13.4 covers foods suitable for people intolerant to gluten as defined by Regulation (EC) No 41/2009. This Regulation was repealed by Regulation (EU) No 609/2013. Since category 13 covers foods for special purposes within the scope of Regulation (EU) No 609/2013 and that Regulation does not cover foods suitable for people intolerant to gluten, this food category should be moved to food category 18 as a new subcategory 18.3.

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, ELI: <http://data.europa.eu/eli/dir/2006/125/oj>).

⁶ Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (OJ L 136, 25.5.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/432/oj>).

- (12) Due to the creation of new food categories 18.2 and 18.3, it is necessary to create a new food category 18.1 covering processed foods not covered by categories 18.2 and 18.3, excluding foods for infants and young children.
- (13) The changes to the food categories in Part E of Annex II to Regulation (EC) No 1333/2008 introduced by this Regulation should be reflected in Part 5, Sections A and B, of Annex III to Regulation (EC) No 1333/2008. That Annex should therefore be amended accordingly.
- (14) Regulation (EC) No 1333/2008 should therefore be amended accordingly.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

Article 2

Annex III to Regulation (EC) No 1333/2008 is amended in accordance with Annex II to this Regulation.

Article 3

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,

For the Commission
The President
Ursula VON DER LEYEN