



Council of the  
European Union

000116/EU XXVI. GP  
Eingelangt am 09/11/17

Brussels, 9 November 2017  
(OR. en)

14171/17

DENLEG 99  
AGRI 616  
SAN 407

#### COVER NOTE

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From:	European Commission
date of receipt:	8 November 2017
To:	General Secretariat of the Council

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No. Cion doc.:	D052936/02
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sweeteners in fine bakery wares

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Delegations will find attached document D052936/02.

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Encl.: D052936/02



Brussels, **XXX**  
SANTE/10217/2017  
(POOL/E2/2017/10217/10217-EN.doc)  
D052936/02  
[...](2017) **XXX**

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

**of **XXX****

**amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sweeteners in fine bakery wares**

(Text with EEA relevance)

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

of **XXX**

**amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sweeteners in fine bakery wares**

(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 additives<sup>1</sup>, 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 flavourings<sup>2</sup>, 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.
- (2) That list may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.
- (3) On the basis of the information provided by the Member States, the Commission has concluded that Annex II to Regulation (EC) No 1333/2008 should be amended as regards the use of E 950 Acesulfame K, E 951 Aspartame, E952 Cyclamic acid and its Na and Ca salts, E 954 Saccharin and its Na, K and Ca salts, E 955 Sucralose, E 959 Neohesperidine DC, E 961 Neotame, E 962 Salt of aspartame-acesulfame and E 969 Advantame in 'fine bakery products for special nutritional uses'.
- (4) The use of sweeteners in 'fine bakery products for special nutritional uses' was authorised by the European Parliament and Council Directive 94/35/EC<sup>3</sup>. The food 'fine bakery products for special nutritional uses' covered 'foods for persons suffering from carbohydrate metabolism disorders (diabetes)' regulated by Council Directive 89/398/EEC<sup>4</sup>. This Directive established a common definition for 'foodstuffs for particular nutritional uses' and provided that specific provisions could be adopted as regards 'food for persons suffering from carbohydrate metabolism disorders (diabetes)', a category of food falling within the definition of foodstuffs for particular nutritional uses.

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<sup>1</sup> OJ L 354, 31.12.2008, p. 16.

<sup>2</sup> OJ L 354, 31.12.2008, p. 1.

<sup>3</sup> European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs (OJ L 237, 10.9.1994, p. 3).

<sup>4</sup> Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (OJ L 186, 30.6.1989, p. 27).

- (5) However, as concluded in the Commission's report<sup>5</sup> on foods for persons suffering from diabetes, the scientific basis for setting specific compositional requirements for those foods was lacking. Furthermore, Regulation (EU) No 609/2013 of the European Parliament and of the Council<sup>6</sup> has abolished the concept of 'foodstuffs for particular nutritional uses', including that of 'food for persons suffering from carbohydrate metabolism disorders (diabetes)'.
- (6) Therefore, the authorisation of those sweeteners in 'fine bakery products for special nutritional uses' in accordance with Article 7(c) of Regulation (EC) No 1333/2008 is no longer justified and those products should not continue to be marketed.
- (7) Furthermore, uniform application of the conditions for authorisation of use of sweeteners would ensure clarity and the proper functioning of the internal market.
- (8) Therefore, the entries for food additives E 950 Acesulfame K, E 951 Aspartame, E952 Cyclamic acid and its Na and Ca salts, E 954 Saccharin and its Na, K and Ca salts, E 955 Sucralose, E 959 Neohesperidine DC, E 961 Neotame, E 962 Salt of aspartame-acesulfame and E 969 Advantame referring to the use in 'only fine bakery products for special nutritional uses' in food category 07.2 fine bakery wares should be deleted.
- (9) Annex II to Regulation (EC) No 1333/2008 should therefore be amended accordingly.
- (10) In order to allow economic operators to adapt to the new rules, it is appropriate to provide for a transitional period during which fine bakery products for special nutritional uses containing any of those sweeteners may continue to be marketed.
- (11) 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 the Annex to this Regulation.

#### *Article 2*

Fine bakery products for special nutritional uses containing E 950 Acesulfame K, E 951 Aspartame, E952 Cyclamic acid and its Na and Ca salts, E 954 Saccharin and its Na, K and Ca salts, E 955 Sucralose, E 959 Neohesperidine DC, E 961 Neotame, E 962 Salt of aspartame-acesulfame and/or E 969 Advantame that have been lawfully placed on the market before the entry into force of this Regulation, may continue to be marketed until the stocks are exhausted.

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<sup>5</sup> [Report](#) from the Commission to the European Parliament and the Council on foods for persons suffering from carbohydrate metabolism disorders (diabetes) of 1 July 2008 (COM(2008) 392 final).

<sup>6</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).

*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*  
*Jean-Claude JUNCKER*