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| From:            | European Commission  |
| date of receipt: | 3 March 2014   |
| To:              | Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union |

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| Subject:       | COMMISSION REGULATION (EU) No .../.. of XXX amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of Advantame as a sweetener |

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Delegations will find attached document D031989/02.

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Encl.: D031989/02



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[...](2014) **XXX**

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

**of **XXX****

**amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of Advantame as a sweetener**

(Text with EEA relevance)

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

of **XXX**

**amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of Advantame as a sweetener**

(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 Articles 10(3) and 14 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 foods and their conditions of use.
- (2) Commission Regulation (EU) No 231/2012<sup>3</sup> lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (3) Those lists 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.
- (4) An application for authorisation of the use of Advantame as a sweetener in several food categories was submitted in May 2010. The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) There is a technological need for the use of Advantame as a high-intensity sweetener in various food and tabletop products in order to replace caloric sugars (sucrose,

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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> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

glucose, fructose, etc.) thus allowing for a reduction of the caloric content of those foodstuffs. The addition of Advantame as a sweetener to the categories of foods in which high-intensity sweeteners are authorised according to Annex II to Regulation (EC) No 1333/2008 will provide manufacturers with greater flexibility in formulating energy-reduced foods with a similar taste profile as the full-caloric equivalent. The flavour and sweetness qualities of Advantame, coupled with good stability characteristics, mean that Advantame provides an alternative to already approved high-intensity sweeteners, offering consumers and the food industry the option to choose from a wider selection of sweeteners, thus reducing the intake of each individual sweetener.

- (6) The European Food Safety Authority ('the Authority') evaluated the safety of Advantame when used as a food additive and expressed its opinion on 31 July 2013<sup>4</sup>. The Authority established an Acceptable Daily Intake (ADI) for Advantame of 5 mg/kg bw/day. Conservative estimates of advantame exposure for high level adults and children consumers were below the ADI for the proposed use levels. After considering all the data on stability, degradation products, toxicology and exposure, the Authority concluded that Advantame would not be of safety concern at the proposed uses and use levels as a sweetener.
- (7) Therefore, it is appropriate to authorise the use of Advantame as a sweetener in the food categories specified in Annex I to this Regulation and to assign E 969 as an E-number to that food additive.
- (8) The specifications for Advantame should be included in Regulation (EU) No 231/2012 when it is included in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.
- (9) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (10) 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*

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

#### *Article 2*

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

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<sup>4</sup> EFSA Journal 2013; 11(7):3301.

*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*  
*José Manuel BARROSO*