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[...](2016) **XXX** draft

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 Steviol glycosides (E 960) as a sweetener in certain energy-reduced confectionery products

(Text with EEA relevance)

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(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,

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 of the European Parliament and of the Council² either on the initiative of the Commission or following an application.
- (3) On 27 May 2015 an application was submitted for authorisation of the use of steviol glycosides (E 960) as a sweetener in certain energy-reduced confectionery products falling under the food subcategory 05.2 ‘Other confectionery including breath freshening microsweets’ of Annex II to Regulation (EC) No 1333/2008. The application was subsequently made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (4) Steviol glycosides are non-caloric sweet-tasting constituents and may be used to replace caloric sugars in certain confectionery products, thus reducing the caloric content of those and offering consumers energy-reduced products, in accordance with Article 7 of Regulation (EC) No 1333/2008. The combined use of steviol glycosides and sugar provide sweetness to products and an improved taste profile compared to products which use only steviol glycosides for sweetening purposes.
- (5) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of the European Food Safety Authority (‘the Authority’) in order to update the Union list of food additives set out in Annex II to Regulation (EC) No 1333/2008.
- (6) In 2010, the Authority adopted a scientific opinion³ on the safety of steviol glycosides for the proposed uses as a food additive (E 960) and established an Acceptable Daily Intake (ADI) of 4 mg/kg body weight/day, expressed as steviol equivalents. In 2015

¹ OJ L 354, 31.12.2008, p. 16.

² 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 (OJ L 354, 31.12.2008, p. 1).

³ EFSA Journal 2010;8(4):1537.

the Authority revised the exposure assessment of steviol glycosides and concluded that the exposure estimates are below the ADI for all age groups, except for toddlers at the upper range of the high level (95th percentile) estimates, in one country.⁴ Exposure calculations carried out by Rijksinstituut voor Volksgezondheid en Milieu in 2015 showed that the proposed extension of use, assuming a market share of 25% for E960 containing products and assuming 100% brand loyalty, did not affect the 95th percentile of exposure in young children aged two to six years in the Netherlands.

- (7) In its latest assessment from 2015 the Authority indicated that it was not possible within the FoodEx classification system to reflect all the restrictions/exceptions applying to the use of steviol glycosides (E 960) in the foods under food subcategory 05.2 and their maximum levels; therefore, the highest maximum level of 2000 mg/kg was assigned to the entire food category resulting in an overestimation of exposure. Additionally, foods of category 05.2. 'Other confectionery including breath freshening microsweets' were not identified as one of the main food categories contributing to exposure to steviol glycosides (E 960).
- (8) Considering that the exposure estimates are below the ADI for all age groups the proposed uses and use levels of steviol glycosides (E 960) as a sweetener are not of a safety concern.
- (9) Therefore, it is appropriate to authorise the use of steviol glycosides (E 960) as a sweetener in certain energy-reduced confectionery products in food subcategory 05.2 'Other confectionery including breath freshening microsweets': hard confectionery (candies and lollies), soft confectionery (chewing candies, fruit gums and foam sugar products/marshmallows), liquorice, nougat and marzipan (at maximum level of 350 mg/kg); strongly flavoured freshening throat pastilles (at maximum level of 670 mg/kg) and breath freshening micro-sweets (at maximum level of 2000 mg/kg).
- (10) Therefore, Annex II to Regulation (EC) No 1333/2008 should be amended accordingly.
- (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

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

⁴ EFSA Journal 2015;13(6):4146.

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