



Council of the  
European Union

Brussels, 13 January 2016  
(OR. en)

5241/16

DENLEG 4  
AGRI 11  
SAN 9

#### COVER NOTE

---

From:	European Commission
date of receipt:	13 January 2016
To:	General Secretariat of the Council

---

No. Cion doc.:	D042508/03
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 Steviol glycosides (E 960) as a sweetener in certain energy-reduced or with no added sugars beverages

---

Delegations will find attached document D042508/03.

---

Encl.: D042508/03



Brussels, **XXX**  
SANTE/12107/2015 CIS  
(POOL/E7/2015/12107/12107-EN  
CIS.doc) D042508/03  
[...](2015) **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 or with no added sugars beverages**

(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 Steviol glycosides (E 960) as a sweetener in certain energy-reduced or with no added sugars beverages**

(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,

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 Council<sup>2</sup> either on the initiative of the Commission or following an application.
- (3) On 25 March 2013 an application was submitted for authorisation of the use of steviol glycosides (E 960) as a sweetener in certain energy-reduced or with no added sugars beverages falling under the food subcategory 14.1.5.2 'Other' 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 beverages, thus reducing the caloric content of those products. Consequently, steviol glycosides provide sweetness to those beverages without delivering additional calories to the final product, offering consumers energy-reduced or with no added sugars products, in accordance with Article 7 of Regulation (EC) No 1333/2008.

---

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

<sup>2</sup> 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).

- (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 opinion<sup>3</sup> 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 view of the proposed extension of uses as a food additive, the Authority revised the exposure assessment of steviol glycosides and expressed its opinions on 2 May 2014<sup>4</sup> and on 30 June 2015<sup>5</sup>. As regards those extensions of uses, the Authority 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. Exposure calculations carried out by Rijksinstituut voor Volksgezondheid en Milieu showed that the proposed extension of use did not affect the 95th percentile of exposure in young children aged two to six years in the Netherlands and that non-alcoholic beverages and flavoured fermented milk products remained the main contributors to exposure to steviol glycosides in that age group.
- (7) Considering that food subcategory 14.1.5.2 covers products not intended to be consumed by toddlers (12 to 35 months old) the proposed uses and use levels of steviol glycosides (E 960) as a sweetener are not of a safety concern.
- (8) Therefore, it is appropriate to authorise the use of steviol glycosides (E 960) as a sweetener added to the energy-reduced or with no added sugars beverages in food subcategory 14.1.5.2 "Other": coffee, tea and herbal infusion beverages (at maximum level of 30 mg/l), flavoured instant coffee and instant cappuccino products (at maximum level of 30 mg/l) and malt-based and chocolate/cappuccino flavoured drinks (at maximum level of 20 mg/l).
- (9) Therefore, Annex II to Regulation (EC) No 1333/2008 should be amended accordingly.
- (10) 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*.

---

<sup>3</sup> EFSA Journal 2010;8(4):1537.

<sup>4</sup> EFSA Journal 2014;12(5):3639.

<sup>5</sup> 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*