



Council of the
European Union

Brussels, 25 July 2016
(OR. en)

11462/16

DENLEG 68
AGRI 429
SAN 301

COVER NOTE

From:	European Commission
date of receipt:	22 July 2016
To:	General Secretariat of the Council

No. Cion doc.:	D045949/02
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 Sucralose (E 955) as a flavour enhancer in chewing gum with added sugars or polyols

Delegations will find attached document D045949/02.

Encl.: D045949/02



Brussels, **XXX**
SANTE/10629/2016
(POOL/E2/2016/10629/10629-EN.doc)
D045949/02
[...](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 Sucralose (E 955) as a flavour enhancer in chewing gum with added sugars or polyols

(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 Sucralose (E 955) as a flavour enhancer in chewing gum with added sugars or polyols

(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 19 January 2015 an application was submitted for authorisation of the use of sucralose (E 955) as a flavour enhancer in chewing gum with added sugars or polyols. The application was subsequently made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (4) Sucralose was evaluated in 2000 by the European Union Scientific Committee on Food (SCF) which established an acceptable daily intake (ADI) of 15 mg/kg body weight/day³.
- (5) The use of sucralose (E 955) as a flavour enhancer in chewing gum with added sugars or polyols increases the overall intensity of the flavour of the chewing gum, and maintains that intensity over a longer period of time as the gum is chewed, compared to other food additive(s) formulations. Increasing the intensity and longevity of the

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 Opinion of the Scientific Committee on Food on sucralose (Adopted by the SCF on 7 September 2000) Available online: http://ec.europa.eu/food/fs/sc/scf/out68_en.pdf

flavour thus provides the consumer with a better overall experience whilst chewing the gum.

- (6) Authorising sucralose at 1200 mg/kg in chewing gum with added sugars or polyols would lead to an increase in the intake of E955 within the following limits: between 0 up to 0,1% of the ADI in the case of mean consumption and between 0 up to 4,3% of the ADI in the case of high level consumption. This is considered to be an additional minor exposure of the consumer and therefore is not of safety concern.
- (7) 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, except where that update is not liable to have an effect on human health. Since the authorisation of use of sucralose (E 955) as a flavour enhancer in chewing gum with added sugars or polyols constitutes an update of that list which is not liable to have an effect on human health, it is not necessary to seek the opinion of the Authority.
- (8) Therefore, it is appropriate to authorise the use of sucralose (E 955) as a flavour enhancer at a maximum level of 1200 mg/kg in chewing gum with added sugars or polyols (food subcategory 5.3).
- (9) Annex II to Regulation (EC) No 1333/2008 should therefore 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*.

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