



Council of the
European Union

Brussels, 19 February 2016
(OR. en)

6315/16

DENLEG 11
AGRI 81
SAN 58

COVER NOTE

From:	European Commission
date of receipt:	18 February 2016
To:	General Secretariat of the Council

No. Cion doc.:	D043700/03
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 Propionic acid – propionates (E 280 – 283) in tortillas

Delegations will find attached document D043700/03.

Encl.: D043700/03



Brussels, **XXX**
SANTE/12485/2015
(POOL/E2/2015/12485/12485-EN.doc)
D043700/03
[...](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 Propionic acid – propionates (E 280 – 283) in tortillas

(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 Propionic acid – propionates (E 280 – 283) in tortillas

(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),

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) The Union list of food additives 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 14 July 2015, an application was submitted for an extension of use of calcium propionate (E282) as a preservative for extension of the shelf-life of tortillas. That application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (4) The use of Propionic acid – propionates is needed for the extension of the shelf-life of tortillas, since this product gets spoiled very quickly due to high moisture content and composition that is susceptible for microbial growth.
- (5) Propionic acid – propionates are widely used to prevent the growth of moulds in leavened bakery products, due to their minimal effect on yeast and on the odour or taste of the final product.
- (6) The European Food Safety Authority ('the Authority'), in its opinion on the re-evaluation of propionic acid (E 280), sodium propionate (E 281), calcium propionate

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).

(E 282) and potassium propionate (E 283) as food additives³, concluded that there would not be a safety concern from the maximum concentrations of those substances at their currently authorised uses and use levels as food additives. The authorisation of the use of propionates in tortillas is an extension which would not lead to additional concern as the exposure assessment done by the Authority covered food category 07.1 Bread and rolls.

- (7) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of 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 such update is not liable to have an effect on human health. Since the extension of the use of Propionic acid – propionates (E 280 – 283) as preservatives in tortillas 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, Annex II to Regulation (EC) No 1333/2008 should be amended accordingly.
- (9) 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 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

³ EFSA Journal 2014;12(7):3779.