



Council of the
European Union

Brussels, 6 November 2015
(OR. en)

13762/15

DENLEG 142
AGRI 575
SAN 367

COVER NOTE

From:	European Commission
date of receipt:	4 November 2015
To:	General Secretariat of the Council

No. Cion doc.:	D041398/02
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 extracts of rosemary (E 392) in spreadable fats

Delegations will find attached document D041398/02.

Encl.: D041398/02



Brussels, **XXX**
SANTE/11284/2015
(POOL/E7/2015/11284/11284-EN.doc)
D041398/02
[...] (2015) **XXX**

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 extracts of rosemary (E 392) in spreadable fats

(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 extracts of rosemary (E 392) in spreadable fats

(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 18 April 2013 an application was submitted for the authorisation of the use of extracts of rosemary (E 392) as an antioxidant in spreadable fats, i.e. in foods falling under the food category 02.2.2 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) According to the application the use of extracts of rosemary (E 392) is required to keep the quality and stability of spreadable fats with a fat content less than 80% where content of polyunsaturated fatty acids is higher than 15% w/w of the total fatty acid and/or where content of fish oil or algal oil is higher than 2% w/w of the total fatty acid by protecting them against deterioration caused by oxidation.
- (5) On 7 March 2008 the European Food Safety Authority ('the Authority') adopted an opinion³ on the use of rosemary extracts as a food additive. Based on the margins of

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 (2008) 721, 1-29.

safety identified using the NOAELs⁴ from the different studies, in which generally the NOAELs were the highest dose levels tested, and using the conservative dietary exposure estimates it was concluded that the use of the rosemary extracts described in that scientific opinion at the proposed uses and use levels would not be of safety concern. The use of extracts of rosemary (E 392) in spreadable fats was not included in the opinion.

- (6) On 7 May 2015 the Authority issued an opinion⁵ on the extension of use of extracts of rosemary (E 392) in spreadable fats. The assessment took into account the consumption of fat emulsions with a fat content less than 80%. The Authority concluded that the proposed extension of use would not change the estimated exposure to the food additive, compared with the already approved permitted uses, and that the conclusions of the opinion of 7 March 2008 remain valid.
- (7) For that reason, it is appropriate to authorise the use of extracts of rosemary (E 392) as an antioxidant in spreadable fats with a fat content less than 80%, food category 02.2.2 of Annex II to Regulation (EC) No 1333/2008.
- (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 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

⁴ NOAEL (no observed adverse effect level) — dose or concentration of a substance tested at which no adverse effect is found.

⁵ EFSA Journal 2015;13(5):4090.