



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 10 September 2012

13480/12

**DENLEG 80
AGRI 553**

COVER NOTE

from: European Commission

date of receipt: 22 August 2012

to: General Secretariat of the Council

No Cion doc.: D021996/02

Subject: COMMISSION REGULATION (EU) No .../.. 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 fillings of stuffed dry pasta

Delegations will find attached Commission document D021996/02.

Encl.: D021996/02



EUROPEAN COMMISSION

Brussels, **XXX**
SANCO/11176/2012
(POOL/E3/2012/11176/11176-EN.doc)
D021996/02
[...](2012) **XXX** draft

COMMISSION REGULATION (EU) No .../..

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 fillings of stuffed dry pasta

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

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 fillings of stuffed dry pasta

(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) and Article 30(5) thereof,

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) That list may be amended in accordance with the procedure referred to in 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 flavourings².
- (3) Pursuant to Article 3(1) of Regulation (EC) No 1331/2008, the Union list of food additives may be updated either on the initiative of the Commission or following an application.
- (4) An application for authorisation of the use of Extracts of rosemary (E 392) as an antioxidant in fillings of stuffed dry pasta was submitted and has been made available to the Member States.
- (5) Antioxidants are substances which protect food against deterioration caused by oxidation, such as fat rancidity and colour changes. Extracts of rosemary (E 392) used in fillings of stuffed dry pasta improve the stability of fats and oils in the recipe (e.g. vegetable oil, fat in meat, cheese and dairy ingredients) during the whole product shelf life. The taste of filled dry pasta is more stable without organoleptic defects and off-notes caused by the fat oxidation.

¹ OJ L 354, 31.12.2008, p. 16.

² OJ L 354, 31.12.2008, p. 1.

- (6) The European Food Safety Authority assessed the use of rosemary extracts as a food additive³. Based on the margins of 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 the scientific opinion at the proposed uses and use levels would not be of safety concern. The additional intake based on the new use in fillings of stuffed dry pasta does not significantly contribute to the overall intake. It is therefore appropriate to allow the use of Extracts of rosemary (E 392) as an antioxidant in fillings of stuffed dry pasta.
- (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 in order to update the Union list of food additives set out in Annex II to Regulation (EC) No 1333/2008, except where the update in question is not liable to have an effect on human health. Since the authorisation of use of Extracts of rosemary (E 392) as an antioxidant in fillings of stuffed dry pasta 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 European Food Safety Authority.
- (8) Pursuant to the transitional provisions of Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives⁵, Annex II establishing the Union list of food additives approved for use in foods and conditions of use applies from 1 June 2013. In order to allow the use of Extracts of rosemary (E 392) in fillings of stuffed dry pasta before that date, it is necessary to specify an earlier date of application with regard to this use of that food additive.
- (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 the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with the Annex to this Regulation.

³ The EFSA Journal (2008) 721, 1-29.

⁴ NOAEL (No Observed Adverse Effect Level) - dose or concentration of a substance tested at which no adverse effect is found.

⁵ OJ L 295, 12.11.2011, p. 1.

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
José Manuel BARROSO

ANNEX

In Part E of Annex II to Regulation (EC) No 1333/2008, in the food category 06.4.5 "Fillings of stuffed pasta (ravioli and similar)":

(a) the following entry is inserted after the entry for E 200-203:

"

	E 392	Extracts of rosemary	250	(41) (46)	only in fillings of stuffed dry pasta	Period of application: From [date of entry into force of this Regulation]
--	-------	----------------------	-----	-----------	---------------------------------------	--

"

(b) the following footnotes are added after footnote (2):

"

(41): Expressed on fat basis
(46): As the sum of carnosol and carnosic acid

"