



Council of the
European Union

Brussels, 16 January 2018
(OR. en)

5369/18

DENLEG 6
AGRI 27
SAN 16

COVER NOTE

From:	European Commission
date of receipt:	12 January 2018
To:	General Secretariat of the Council

No. Cion doc.:	D053886/02
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 polyglycerol polyricinoleate (E 476) in emulsified sauces

Delegations will find attached document D053886/02.

Encl.: D053886/02



Brussels, **XXX**
SANTE/11396/2017
(POOL/E2/2017/11396/11396-EN.doc)
D053886/02
[...](2017) **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 polyglycerol polyricinoleate (E 476) in emulsified sauces

(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 polyglycerol polyricinoleate (E 476) in emulsified sauces

(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 foods 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) According to Annex II to Regulation (EC) No 1333/2008 polyglycerol polyricinoleate (E 476) is an already authorised food additive in food category 12.6 ‘Sauces’ (at a maximum level of 4 000 mg/kg), but only for dressings.
- (4) Pursuant to Article 32(1) of Regulation (EC) No 1333/2008 polyglycerol polyricinoleate (E 476) needs to be subject to a new risk assessment by the European Food Safety Authority (‘the Authority’). Pursuant to Commission Regulation (EU) No 257/2010³ the re-evaluation of emulsifiers had to be completed by 31 December 2016.
- (5) On 4 August 2014, an application was submitted for the authorisation of the use of polyglycerol polyricinoleate (E 476) as an emulsifier in emulsified sauces. The application was subsequently made available to the Member States by the Commission pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (6) Fat reduction in processed food, such as emulsified sauces, is normally achieved by the use of thickeners. However, thickeners lead to an undesirable modification of the organoleptic properties of the food when used above a certain concentration. An

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 Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up the program for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (OJ L 80, 26.3.2010, p. 19).

additional reduction of fat content can be achieved in some foods, such as emulsified sauces, by the use of emulsifiers capable of stabilising a high content of water inside fat. In studies carried out by the applicant comparing the effectiveness of different emulsifiers for further fat reduction in emulsified sauces, polyglycerol polyricinoleate (E 476) gave the best results both in terms of physical as well as organoleptic properties of the obtained emulsified sauce. The level of polyglycerol polyricinoleate (E 476) needed to achieve the intended technological function was 4000 mg/kg.

- (7) On 27 May 2016, the Commission requested the Authority to evaluate the safety of the proposed extension of use of polyglycerol polyricinoleate (E 476) in emulsified sauces in addition to the re-evaluation of the safety of this substance pursuant to Commission Regulation (EU) No 257/2010.
- (8) On 24 March 2017, the Authority delivered a Scientific Opinion on the re-evaluation of polyglycerol polyricinoleate (E 476)⁴ and established an acceptable daily intake (ADI) of 25 mg polyglycerol polyricinoleate/kg body weight/day. Considering that the exposure estimates did not exceed the ADI, the Authority concluded that polyglycerol polyricinoleate (E 476) as a food additive would not be of safety concern if used at the permitted or reported use and use levels. The Authority also concluded that the additional use of polyglycerol polyricinoleate (E 476) at the maximum level of 4000 mg/kg in emulsified sauces would not result in a total exposure to this substance exceeding the ADI. Consequently, the extension of use for polyglycerol polyricinoleate (E 476) in emulsified sauces is not of safety concern.
- (9) In addition, the Authority recommended several amendments to the specifications of polyglycerol polyricinoleate (E 476) in Commission Regulation (EU) No 231/2012⁵. These are to a large extent linked to the use of glycerol in the manufacturing process of polyglycerol polyricinoleate (E 476) and are therefore similar to the recommendations made by the Authority in its Scientific Opinion on the re-evaluation of glycerol (E 422)⁶. Consequently, the amendment of the specifications of polyglycerol polyricinoleate (E 476), in line with the recommendations of the Authority, will be addressed separately, together with the specifications of glycerol (E 422) and of other glycerol-based food additives.
- (10) Therefore, it is appropriate to authorise the use of polyglycerol polyricinoleate (E 476) as an emulsifier in emulsified sauces, including dressings, in food category 12.6 'Sauces' (at a maximum level of 4 000 mg/kg).
- (11) Annex II to Regulation (EC) No 1333/2008 should therefore be amended accordingly.
- (12) 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.

⁴ EFSA Journal 2017;15(3):4743.

⁵ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁶ EFSA Journal 2017;15(3):4720.

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