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Delegations will find attached document D063925/03.

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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 liquid vegetable oil emulsions

(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 liquid vegetable oil emulsions

(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) Pursuant to Annex II to Regulation (EC) No 1333/2008 polyglycerol polyricinoleate (E 476) is an already authorised food additive in food category 02.2.2 ‘Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1234/2007 and liquid emulsions’ (at a maximum level of 4 000 mg/kg), but only for spreadable fats as defined in Article 115 of Council Regulation (EC) No 1234/2007³ and Annex XV thereto, having a fat content of 41 % or less and similar spreadable products with a fat content of less than 10 % fat. Regulation (EC) No 1234/2007 has been later repealed by Regulation (EU) No 1308/2013 of the European Parliament and of the Council⁴.
- (4) On 27 May 2017, an application was submitted for the authorisation of the use of polyglycerol polyricinoleate (E 476) as an emulsifier in liquid vegetable oil emulsions for sale to the final consumer, having a fat content of 70 % or less. The application was subsequently made available to the Member States by the Commission pursuant to Article 4 of Regulation (EC) No 1331/2008.

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 Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) (OJ L 299, 16.11.2007, p. 1).

⁴ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

- (5) Polyglycerol polyricinoleate (E 476) is a water-in-oil emulsifier capable of forming very stable oil emulsions with high water content. In studies carried out by the applicant, comparing the effectiveness of different emulsifiers for the production of liquid vegetable oil emulsions with reduced fat content, polyglycerol polyricinoleate (E 476) gave the best results both in terms of physical as well as organoleptic properties of the obtained product. The emulsion can be used in the same way as vegetable oils for the preparation of cold and hot dishes. However, the emulsion has a lower fat content (70 % or less), and therefore a lower caloric content than the vegetable oil used for its production. The level of use of polyglycerol polyricinoleate (E 476) needed to achieve the intended technological function was 4 000 mg/kg.
- (6) On 24 March 2017, the European Food Safety Authority ('the Authority') delivered a scientific opinion on the re-evaluation of polyglycerol polyricinoleate (E 476)⁵ 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
- (7) In the application the applicant estimated the exposure by using the Food Additives Intake Model⁶ developed by the Authority. The estimates provided indicate that the additional use of polyglycerol polyricinoleate (E 476) at the maximum level of 4 000 mg/kg in liquid vegetable oil emulsions having a fat content of 70 % or less, is not of safety concern, since it would not result in a total exposure to this substance exceeding the established ADI.
- (8) 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 the update in question is not liable to have an effect on human health.
- (9) Since the extended use of polyglycerol polyricinoleate (E 476) in food category 02.2.2 is not of safety concern, it requires an update of the Union list, which is not liable to have an effect on human health and hence it is not necessary to seek the opinion of the Authority.
- (10) Therefore, it is appropriate to authorise the use of polyglycerol polyricinolate (E 476) as an emulsifier in liquid vegetable oil emulsions for sale to the final consumer, having a fat content of 70 % or less, in food category 02.2.2 'Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1234/2007 and liquid emulsions'.
- (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.

⁵ EFSA Journal 2017;15(3):4743.

⁶ <https://www.efsa.europa.eu/en/applications/foodingredients/tools>

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