



Council of the
European Union

029625/EU XXVI. GP
Eingelangt am 06/07/18

Brussels, 5 July 2018
(OR. en)

10896/18

DENLEG 58
AGRI 347
SAN 218

COVER NOTE

From:	European Commission
date of receipt:	4 July 2018
To:	General Secretariat of the Council
No. Cion doc.:	D056133/02
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards Cochineal, Carminic acid, Carmines (E 120)

Delegations will find attached document D056133/02.

Encl.: D056133/02



Brussels, **XXX**
SANTE/10263/2018
(POOL/E2/2018/10263/10263-EN.doc)
D056133/02
[...](2018) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards Cochineal, Carminic acid, Carmines (E 120)

(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 and the Annex to Commission Regulation (EU) No 231/2012 as regards Cochineal, Carminic acid, Carmines (E 120)

(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 14 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) Commission Regulation (EU) No 231/2012² lays down specifications for food additives that are listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (3) Cochineal, Carminic acid, Carmines (E 120) is a substance authorised as a colour in a variety of foods in accordance with Annex II to Regulation (EC) No 1333/2008.
- (4) Article 32(1) of Regulation (EC) No 1333/2008 provides that all food additives that were already permitted in the Union before 20 January 2009 are subject to a new risk assessment by the European Food Safety Authority ('the Authority').
- (5) For that purpose, a program for the re-evaluation of food additives is laid down in Commission Regulation (EU) No 257/2010³, according to which the re-evaluation of colours had to be completed by 31 December 2015.
- (6) On 18 November 2015 the Authority delivered a Scientific Opinion on the re-evaluation of cochineal, carminic acid, carmines (E 120) as a food additive⁴. The Authority concluded that the present dataset did not give reasons to revise the Acceptable Daily Intake (ADI) value for E 120 and that the refined exposure estimates were below the ADI for all population groups. However, the Authority recommended to revise the current title 'Cochineal, Carminic acid, Carmines', so that it would more accurately reflect the material used as a food additive and to update the specifications

¹ OJ L 354, 31.12.2008, p. 16.

² 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).

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).

⁴ EFSA Journal 2015; 13(11):4288.

as regards the percentage of material not accounted for, the maximum limits for toxic elements and the presence of proteinaceous compounds.

- (7) Pursuant to Article 10(3) of Regulation (EC) No 1333/2008, the Union list of approved food additives shall be amended in accordance with the procedure referred to in Regulation (EC) No 1331/2008 of the European Parliament and of the Council⁵.
- (8) Article 3(1) of Regulation (EC) No 1331/2008 provides that the Union list of food additives may be updated either on the initiative of the Commission or following an application.
- (9) It is therefore appropriate to amend Annex II to Regulation (EC) No 1333/2008 and the Annex to Regulation (EU) No 231/2012.
- (10) A reasonable period should be allowed to elapse before the amendments become applicable in order to permit food business operators to meet the new requirements laid down in this Regulation.
- (11) 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

In Annex II to Regulation (EC) No 1333/2008 whenever a reference is made to ‘E 120 Cochineal, Carminic acid, Carmines’ it shall be replaced by ‘E 120 Carminic acid, Carmine’.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with the Annex to this Regulation.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [Office of Publication please insert the date: 12 months after entry into force.]XX XXXX XXXX.

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

⁵ 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).