Commission Regulation (EU) 2018/1472 of 28 September 2018 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) 2018/1472

of 28 September 2018

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 additives[(1)], 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 231/2012[(2)] 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 257/2010[(3)], 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 additive[(4)]. 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 as regards the percentage of material not accounted for, the maximum limits for toxic elements and the presence of proteinaceous compounds.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/1472. (See end of Document for details)*

(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 Council[(5)].

(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 23 October 2019.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28 September 2018.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2018/1472. (See end of Document for details)*

ANNEX

In the Annex to Regulation (EU) No 231/2012 the entry for ‘E 120 Cochineal, Carminic acid, Carmines’ is replaced by the following:

E 120 CARMINIC ACID, CARMINE	
Synonyms	CI Natural Red 4
Definition	Carminic acid is obtained from aqueous, aqueous alcoholic or alcoholic extracts from Cochineal, which consists of the dried bodies of the female insect Dactylopius coccus Costa. Carmines are aluminium lakes of carminic acid in which aluminium and carminic acid are thought to be present in the molar ratio 1:2. The colouring principle is carminic acid. Minor amounts of its aminated form 4-aminocarminic acid may also be present. In commercial products the colouring principle carminic acid may be present in association with ammonium, calcium, potassium or sodium cations, singly or in combination, and these cations may also be present in excess. Commercial products may also contain proteinaceous material derived from the source insect.
Colour Index No	75470
Einecs	Carminic acid: 215-023-3; carmines: 215-724-4
Chemical name	7-β-D-glucopyranosyl-3,5,6,8-tetrahydroxy-1-methyl-9,10-dioxoanthracene-2-carboxylic acid (carminic acid); carmine is the hydrated aluminium chelate of this acid
Chemical formula	$C_{22}H_{20}O_{13}$ (carminic acid)
Molecular weight	492,39 (carminic acid)
Assay	Content not less than 90 % carminic acid; not less than 50 % carminic acid in the chelates.
Description	Red to dark red, friable, solid or powder
Identification	
Spectrometry	Carminic acid: Maximum in aqueous ammonia solution at ca. 518 nm Maximum in dilute hydrochloric solution at ca. 494 nm E 1 %/1 cm 139 at peak around 494 nm in dilute hydrochloric acid 4-aminocarminic acid: Maximum in aqueous ammonia solution at 535 nm Maximum in dilute hydrochloric solution at 530 nm E 1 %/1 cm 260 at peak around 535 nm in aqueous ammonia solution, pH 9,5