# COMMISSION REGULATION (EU) 2019/800

## of 17 May 2019

## amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the extension of the use of carminic acid, carmine (E 120) in certain meat products traditional in French Overseas Territories

**(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) 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) 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 Council ([2]), either on the initiative of the Commission or following an application.

(3) 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) On 23 June 2017, an application was submitted for the authorisation of the use of carminic acid, carmine (E 120) in certain non-heat-treated meat products. The application was subsequently made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

(5) The applicant requested the authorisation for the use of carminic acid, carmine (E 120) in order to achieve the desired pink colour for certain traditional salted pork offal and beef specialities, such as *groin de porc à la créole, queue de porc à la créole, pied de porc à la créole* and *paleron de bœuf à la créole* to meet the consumer expectations in French Overseas Territories where these products have been part of a culinary tradition since the 18th century.

(6) Carminic acid, carmine (E 120) is added to brine rich in salt into which offal is immersed. In products as marketed, the salt content is at least 70 g per kg of meat so as to safeguard microbiological stability and a long shelf life (often 12 months). Before cooking, the products need to be desalted in water. Carminic acid, carmine (E120) stays mainly on the surface of the meat and its stability to temperature, light, pH and oxygen ensures characteristic appearance even after cooking.

(7) Recital 7 of Regulation (EC) No 1333/2008 stipulates that the approval of food additives should also take into account other factors relevant to the matter under consideration including, inter alia, traditional factors. Therefore, it is appropriate to maintain certain traditional products on the market in some Member States where the use of food additives comply with the general and specific conditions laid down in Regulation (EC) No 1333/2008.

(8) On 18 November 2015, the European Food Safety Authority (the Authority) published a Scientific Opinion re-evaluating the safety of carminic acid, carmine (E 120) as a food additive ([3]). The Authority concluded that there was no reason to revise the acceptable daily intake value (ADI) of 2,5 mg carminic acid/kg bw/day and that the refined exposure estimates for the non-brand-loyal scenario are below the ADI for all population groups. Carminic acid, carmine (E120) is authorised for use in a wide variety of foods. The extended use is proposed for a few niche meat products and at a lower maximum level than the other currently authorised uses in food category 08.3.1 'Non-heat-treated meat products' in Part E of Annex II to Regulation (EC) No 1333/2008. Since according

([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]) EFSA Journal 2015; 13(11):4288.

to the Scientific Opinion meat products are not among the main contributors to the total exposure to carminic acid, carmine (E 120), it is not expected that the proposed use will have a significant impact on the overall exposure which therefore will remain below the ADI.

(9) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission has 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. Since the extended use of carminic acid, carmine (E120) is not liable to have an effect on human health it is not necessary to seek the opinion of the Authority.

(10) Annex II to Regulation (EC) No 1333/2008 should therefore be amended accordingly.

(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*

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

*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, 17 May 2019.

*For the Commission*
*The President*
Jean-Claude JUNCKER

*ANNEX*

In Part E of Annex II to Regulation (EC) No 1333/2008, in food category 08.3.1 'Non-heat-treated meat products', the following new entry for E 120 is inserted after the entry for E 110:

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|---|---|---|---|---|---|
| | 'E 120 | Carminic acid, Carmine | 50 | | only the following traditional salted pork offal and beef specialties: *groin de porc à la créole, queue de porc à la créole, pied de porc à la créole* and *paleron de bœuf à la créole*. These products are consumed after desalting and cooking.' |