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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	13 January 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	D102136/02
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EC) No 1333/2008 as regards the use of mono- and diglycerides of fatty acids (E 471) and carnauba wax (E 903) as glazing agents on certain fresh fruit and cassavas and of lecithins (E 322) and fatty acids (E 570) as carriers in glazing agents on cassavas

Delegations will find attached document D102136/02.

Encl.: D102136/02



EUROPEAN
COMMISSION

Brussels, **XXX**
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[...] (2024) **XXX** draft

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

of **XXX**

amending Regulation (EC) No 1333/2008 as regards the use of mono- and diglycerides of fatty acids (E 471) and carnauba wax (E 903) as glazing agents on certain fresh fruit and cassavas and of lecithins (E 322) and fatty acids (E 570) as carriers in glazing agents on cassavas

(Text with EEA relevance)

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

of **XXX**

amending Regulation (EC) No 1333/2008 as regards the use of mono- and diglycerides of fatty acids (E 471) and carnauba wax (E 903) as glazing agents on certain fresh fruit and cassavas and of lecithins (E 322) and fatty acids (E 570) as carriers in glazing agents on cassavas

(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, and in particular Articles 10(3) thereof,

Having regard to 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, and in particular Article 7(5) 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. Annex III to that Regulation lays down a Union list of food additives, including carriers approved for use in food additives, food enzymes, food flavourings, nutrients and their conditions of use.
- (2) The Union list of food additives may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application from a Member State or an interested party.
- (3) Lecithins (E 322), mono- and diglycerides of fatty acids (E 471), fatty acids (E 570) and carnauba wax (E 903) are substances authorised in accordance with Regulation (EC) No 1333/2008. In the food category 04.1.1 'Entire fresh fruit and vegetables' in Annex II to Regulation (EC) No 1333/2008, mono- and diglycerides of fatty acids (E 471) are authorised as glazing agent for the surface treatment of certain fruit, and carnauba wax (E 903) is authorised as glazing agent for the surface treatment of the same or other fruit. Lecithins (E 322) and fatty acids (E 570) are included among carriers authorised for use in glazing agents for fruit in Part 1 of Annex III to Regulation (EC) No 1333/2008.
- (4) On 5 November 2020, an application was submitted for the authorisation of the use of mono- and diglycerides of fatty acids (E 471) as a glazing agent on passionfruit, kiwis, apples, pears, peaches, nectarines, plums, cherries, strawberries, blueberries, cucumbers, asparagus, tomatoes and peppers. The application was subsequently made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) On 20 May 2023, applications were submitted for the authorisation of the use of mono- and diglycerides of fatty acids (E 471) and carnauba wax (E 903) as glazing

agents on cassavas and for the authorisation of the use of lecithins (E 322) and fatty acids (E 570) as carriers in glazing agents for cassavas. The applications were subsequently made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

- (6) According to the applicants, the proposed use of mono- and diglycerides of fatty acids (E 471) and carnauba wax (E 903) would address an increasing demand for year-round availability of fresh produce, reduce food waste and improve the efficiency of natural resource use in agricultural production through reduced losses and use of lower carbon dioxide emission methods of transportation.
- (7) Mono- and diglycerides of fatty acids (E 471) and carnauba wax (E 903), when used as glazing agents for a surface treatment of fresh fruit and vegetables, form a thin, inert, physical barrier layer against moisture loss and oxidation to protect the nutritional quality and extend the shelf-life of those products.
- (8) Lecithins (E 322) and fatty acids (E 570), when used as carriers, facilitate the formation of stable and uniform coatings of glazing agents applied to fruit and cassavas.
- (9) Pursuant to Article 15 of Regulation (EC) No 1333/2008, food additives are not to be used in unprocessed foods, except where such use is specifically provided for in Annex II.
- (10) Consumers do not expect the use of food additives on fresh fruit and vegetables and there is no obligation in the Union legislation to inform about food additives used on such products. However, glazing agents are applied to the peel of the fruit or vegetable and are not expected to migrate into their internal parts. Therefore, since the peels of passion fruit, kiwis and cassavas are normally not consumed, such products even if treated with glazing agents do not contain, as ingested, glazing agents.
- (11) Furthermore, the use of glazing agents on such products may be particularly needed since in particular passion fruit and cassavas are mainly produced in areas with a warm climate and may be subject to a long transportation and storage in those areas before being placed on the Union market.
- (12) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission has to seek the opinion of the European Food Safety Authority ('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.
- (13) On 4 October 2012, the Authority issued a scientific opinion on the re-evaluation of carnauba wax (E 903) as a food additive¹, which concluded that the currently authorised uses would not be of safety concern.
- (14) On 7 April 2017, the Authority issued a scientific opinion on the re-evaluation of lecithins (E 322) as a food additive², which concluded that there was no need for a numerical acceptable daily intake and that the additive was of no safety concern for the general population. Such conclusion is used for substances of a very low safety concern and only if there is reliable information for both exposure and toxicity and

¹ EFSA Journal 2012; 10[10]:2880.

² EFSA Journal 2017; 15[4]:4742.

there is a low probability of adverse health effects in humans at doses that do not induce nutritional imbalance in animals³.

- (15) On 5 May 2017, the Authority issued a scientific opinion on the re-evaluation of fatty acids (E 570) as a food additive⁴, which concluded that there was no safety concern at the reported uses and use levels.
- (16) On 10 November 2017, the Authority issued a scientific opinion on the re-evaluation of mono- and diglycerides of fatty acids (E 471) as food additives⁵, which concluded that there was no need for a numerical acceptable daily intake and that the food additive was of no safety concern when used in food for the general population.
- (17) Furthermore, as the peels of passion fruit, kiwis and cassavas are normally not consumed and mono- and diglycerides of fatty acids (E 471), carnauba wax (E 903), lecithins (E 322) and fatty acids (E 570) are not expected to migrate into their internal edible parts when used, respectively, as or in glazing agents for surface treatment, such use is not liable to have an effect on human health. It is thus not necessary to seek the opinion of the Authority.
- (18) It is therefore appropriate to authorise the use of mono- and diglycerides of fatty acids (E 471) on passion fruit, kiwis and cassavas, the use of carnauba wax (E 903) on cassavas and the use of lecithins (E 322) and fatty acids (E 570) in glazing agents for cassavas.
- (19) Therefore, Annexes II and III to Regulation (EC) No 1333/2008 should be amended accordingly.
- (20) 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 I to this Regulation.

Article 2

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

³ EFSA Journal 2014; 12[6]: 3697.

⁴ EFSA Journal 2017; 15[5]:4785.

⁵ EFSA Journal 2017; 15[11]:5045.

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN