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Delegations will find attached document D060704/02.

Encl.: D060704/02



Brussels, **XXX**
SANTE/11629/2018
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[...] (2019) **XXX** draft

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 mono- and diglycerides of fatty acids (E 471) on certain fresh fruits

(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 mono- and diglycerides of fatty acids (E 471) on certain fresh fruits

(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 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 Council², either on the initiative of the Commission or following an application.
- (3) Mono- and diglycerides of fatty acids (E 471) is a food additive authorised in a variety of foods in accordance with Annex II to Regulation (EC) No 1333/2008.
- (4) On 17 February 2017, an application was submitted for the authorisation of the use of mono- and diglycerides of fatty acids of fatty acids (E 471) on all fresh fruits and vegetables. The application was subsequently made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) Mono- and diglycerides of fatty acids (E 471), when used as a glazing agent for a surface treatment of fresh fruits and vegetables, form a thin, inert, physical barrier layer against moisture loss and oxidation to protect the nutritional quality and extend the shelf life. According to the applicant, the proposed use 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.
- (6) The application was discussed by the Working Party of Governmental Experts on Additives. The Working Party noted that there is a technological need in particular for the external treatment of certain fruits which are mainly imported from countries with a tropical climate and which need to be protected during long transports. Peels of those fruits are usually not consumed.

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).

- (7) On 10 November 2017, the European Food Safety Authority ('the Authority') published a scientific opinion re-evaluating the safety of mono- and diglycerides of fatty acids (E 471) as food additives³. The Authority concluded that there was no need for a numerical acceptable daily intake and that the food additive mono- and diglycerides of fatty acids (E 471) was of no safety concern at the reported uses and use levels. 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 there is a low probability of adverse health effects in humans at doses that do not induce nutritional imbalance in animals⁴. However, the Authority recommended some modifications of the EU specifications for the food additive mono- and diglycerides of fatty acids (E 471). The Commission will address these recommendations separately following the general approach for the Authority's opinions in which some concerns have been identified⁵.
- (8) In addition, mono- and diglycerides of fatty acids (E 471) are intended to be used for the external treatment and are not expected to migrate into the internal edible part of the fruits. The treatment on fruits of which the peels are usually not consumed is not liable to have an effect on human health. It is therefore appropriate to allow the use of mono- and diglycerides of fatty acids (E 471) on certain fruits that are mainly imported from countries with a tropical/subtropical climate and of which peels are usually not consumed, i.e. citrus fruit, melons, pineapples, bananas, papayas, mangoes, avocados and pomegranates.
- (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 authorisation of use of mono- and diglycerides of fatty acids (E 471) on citrus fruit, melons, pineapples, bananas, papayas, mangoes, avocados and pomegranates constitutes an update of that list which 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*.

³ EFSA Journal 2017;15(11):5045

⁴ EFSA Journal 2014;12(6):3697, Statement on a conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EU) No 257/2010.

⁵ <https://ec.europa.eu/food/sites/food/files/safety/docs/fs-improv-approach.pdf>

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*