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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 the food additive stearyl tartrate (E 483)

Delegations will find attached document D089305/03.

Encl.: D089305/03



EUROPEAN
COMMISSION

Brussels, **XXX**
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[...](2023) **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 the food additive stearyl tartrate (E 483)

(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 the food additive stearyl tartrate (E 483)

(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,

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 flavourings², 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.
- (2) Pursuant to Article 3(1) of Regulation (EC) No 1331/2008, the Union list of food additives may be updated either on the initiative of the Commission or following an application
- (3) Commission Regulation (EU) No 231/2012³ lays down specifications for food additives that are listed in Annex II to Regulation (EC) No 1333/2008.
- (4) Stearyl tartrate (E 483) is a substance authorised in certain foods in accordance with Annex II to Regulation (EC) No 1333/2008.
- (5) On 11 March 2020, the European Food Safety Authority ('the Authority') issued a scientific opinion on the re-evaluation of stearyl tartrate (E 483) as a food additive⁴. The opinion stated that there was a lack of adequate toxicological data on stearyl

¹ OJ L 354, 31.12.2008, p. 16.

² OJ L 354, 31.12.2008, p. 1.

³ 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).

⁴ EFSA Journal 2020;18(3):6033.

tartrate. In addition, adequate data that could allow read-across from data on other substances were lacking. Consequently, the Authority was not able to confirm the safety of stearyl tartrate as a food additive and concluded that the acceptable daily intake (ADI) for this substance could not be confirmed.

- (6) On 19 January 2021, the Commission launched a public call for technical and scientific data on the permitted food additive stearyl tartrate (E 483), targeting the data needs identified by the Authority. However, no business operator committed to provide the requested toxicological data for stearyl tartrate (E 483). Without those data, the Authority cannot complete the re-evaluation of the safety of stearyl tartrate as a food additive. Therefore, it cannot be determined whether this substance still fulfils the conditions pursuant to Article 6(1) of Regulation (EC) No 1333/2008 for inclusion in the Union list of approved food additives.
- (7) It is therefore appropriate to remove stearyl tartrate (E 483) from the Union list of approved food additives.
- (8) Due to the absence of appropriate toxicological data to confirm the safety of stearyl tartrate (E 483) as a food additive, its inclusion in the list of authorised food additives can no longer be justified and stearyl tartrate (E 483) should be deleted from the Union list of authorised food additives. Annex II to Regulation (EC) No 1333/2008 and the Annex to Regulation (EU) No 231/2012 should be amended accordingly.
- (9) In order to enable food business operators to find alternatives to stearyl tartrate (E 483), this Regulation should start to apply six months after the date of its entry into force.
- (10) It is also appropriate to provide for a transitional period during which foods containing stearyl tartrate (E 483) that have been lawfully placed on the market before the date of application of this Regulation may continue to be marketed.
- (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

In the Annex to Regulation (EU) No 231/2012, the entry for the food additive stearyl tartrate (E 483) is deleted.

Article 3

Foods containing stearyl tartrate (E 483) that have been lawfully placed on the market before ... [6 months after the date of entry into force] may continue to be marketed until their date of minimum durability or 'use-by date'.

Article 4

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 ... [6 months after the date of entry into force].

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