Commission Regulation (EU) No 545/2013 of 14 June 2013 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the flavouring substance 3-acetyl-2,5-dimethylthiophene (Text with EEA relevance)

COMMISSION REGULATION (EU) No 545/2013

of 14 June 2013

amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the flavouring substance 3-acetyl-2,5-dimethylthiophene

(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 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC[(1)], and in particular Article 11(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[(2)], and in particular Article 7(6) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) No 872/2012[(3)] has adopted a list of flavouring substances and has introduced that list in Part A of Annex I to Regulation (EC) No 1334/2008.

(2) That list may be updated in accordance with the common procedure referred to in Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application by a Member State or by an interested party.

(3) The flavouring substance 3-acetyl-2,5-dimethylthiophene (FL-no 15.024) is included in the list as a flavouring substance under evaluation for which additional scientific data must be submitted. Such data has been submitted by the applicant.

(4) The European Food Safety Authority has evaluated the submitted data and concluded on 15 May 2013 that 3-acetyl-2,5-dimethylthiophene is mutagenic both *in vitro* and *in vivo* and that therefore its use as flavouring substance raises a safety concern[(4)].

(5) Accordingly the use of 3-acetyl-2,5-dimethylthiophene does not comply with the general conditions of use for flavourings set out in Article 4(a) of Regulation (EC) No 1334/2008. Consequently, that substance should be removed from the list without delay in order to protect human health.

(6) The Commission should use the urgency procedure for the removal of a substance which raises a safety concern from the Union list.

(7) Pursuant to Article 30 of Regulation (EC) No 1334/2008 flavouring substances not included in the Union list may be placed on the market as such and used in or on food until 22 October 2014. That transitional period should not apply to 3-acetyl-2,5-dimethylthiophene.

(8) Due to very low use levels and the low total amount that 3-acetyl-2,5-dimethylthiophene has been added yearly to foods in the European Union, the presence of that substance in food does not raise immediate safety concerns. Therefore, taking into account also technical and economic reasons, transitional periods should be laid down to cover food containing the flavouring substance 3-acetyl-2,5-dimethylthiophene, which has been placed on the market or dispatched from third countries for the Union, before the date of entry into force of this Regulation.

(9) Regulation (EC) No 1334/2008 should therefore be amended accordingly.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Part A of Annex I to Regulation (EC) No 1334/2008 is amended in accordance with the Annex to this Regulation.

Article 2

1 The placing on the market of 3-acetyl-2,5-dimethylthiophene as a flavouring substance and the use of that substance in or on foods shall be prohibited.

2 The placing on the market of food containing the flavouring substance 3-acetyl-2,5-dimethylthiophene shall be prohibited.

3 The import of 3-acetyl-2,5-dimethylthiophene as a flavouring substance and the import of food containing the flavouring substance 3-acetyl-2,5-dimethylthiophene shall be prohibited.

Article 3

1 By way of derogation to Article 2(2), foods containing the flavouring substance 3-acetyl-2,5-dimethylthiophene which have been legally placed on the market before the date of entry into force of this Regulation may be marketed until their ‘use by’ date or their date of minimum durability.

2 Article 2 shall not apply to consignments of food containing the flavouring substance 3-acetyl-2,5-dimethylthiophene where the importer of such food can demonstrate that they have been dispatched from the third country concerned and were en route to the Union before the date of entry into force of this Regulation.

Article 4

This Regulation shall enter into force on the 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, 14 June 2013.

For the Commission

The President

José Manuel BARROSO