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Subject:	COMMISSION REGULATION (EU) No …/.. 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 use of L-leucine as a carrier for table-top sweeteners in tablets

Delegations will find attached document D036697/03.

Encl.: D036697/03

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[…](2014) XXX draft

COMMISSION REGULATION (EU) No …/..

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 use of L-leucine as a carrier for table-top sweeteners in tablets

(Text with EEA relevance)

COMMISSION REGULATION (EU) No …/..

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(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 Articles 10(3), 14 and 30(5) 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(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) Commission Regulation (EU) No 231/2012[3] lays down specifications for food additives that are listed in Annexes II and III to Regulation (EC) No 1333/2008.

(3) Those lists 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.

(4) On 9 September 2010 an application for authorisation of the use of L-leucine as a carrier (tableting aid) for table-top sweeteners in tablets was submitted by Germany where such use was authorised. That application has been made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

(5) There is a technological function and need for the use of L-leucine in table-top sweeteners in tablets. L-leucine is homogeneously mixed with sweeteners before

[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).

pressing tablets from the mixture and it aids tableting by ensuring that the tablets do not remain stuck to the pressing tools.

(6) The European Food Safety Authority ('the Authority') evaluated the safety of amino acids and related substances when used as flavouring substances and expressed its opinion on 29 November 2007[4]. The Authority concluded that the human exposure to amino acids through food is in orders of magnitude higher than the anticipated levels of exposure from their use as flavouring substances and that nine of the substances, including L-leucine, were not of safety concern at their estimated levels of intake as flavouring substances.

(7) It was demonstrated in the application that even a high consumption of sweetener tablets would not exceed 4 % of the intake quantity recommended for L-leucine.

(8) Therefore, it is appropriate to authorise the use of L-leucine as a carrier for table-top sweeteners in tablets as specified in Annex I to this Regulation and to assign E 641 as an E-number to that food additive.

(9) The specifications for L-leucine should be included in Regulation (EU) No 231/2012 when it is included in the Union lists in Annex II to Regulation (EC) No 1333/2008 for the first time. In this regard it is appropriate to take into account the purity criteria of the European Pharmacopoeia for L-leucine.

(10) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plant, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with 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*.

[4] The EFSA Journal (2008) 870, 1-46.

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