COMMISSION REGULATION (EU) No 506/2014

of 15 May 2014

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 Ethyl lauroyl arginate as a preservative in certain heat-treated meat products

(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 Article 10(3), Article 14 and Article 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 listed in Annexes II and III to Regulation (EC) No 1333/2008.

(3) The Union list and the specifications 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 5 May 2006, an application was submitted for authorisation of the use of Ethyl lauroyl arginate as a preservative in several food categories. The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

(5) Subsequently, in April of 2007 the European Food Safety Authority (the Authority) evaluated the safety of the use of Ethyl lauroyl arginate as a food preservative and allocated an Acceptable Daily Intake (ADI) of 0,5 mg/kg body weight ([4]). Conservative estimates of exposure to the substance, both in adults and in children, suggested that it was likely that the ADI would be exceeded at the maximum proposed use levels for several food categories.

(6) Following these conclusions, the applicant revised its uses and use levels and requested an authorisation of the use in heat-treated meat products. In July 2013 the Authority published a statement on a refined exposure assessment of Ethyl lauroyl arginate based on its revised proposed uses as a food additive ([5]), and concluded that the exposure for all population groups is below the Acceptable Daily Intake (ADI) of 0,5 mg/kg bw/day.

(7) There is a technological need to use Ethyl lauroyl arginate as a preservative in heat-treated meat products in order to improve the microbiological quality of those food products, including inhibiting the growth of harmful micro-organisms such as *Listeria monocytogenes*. As the use of Ethyl lauroyl arginate in heat treated meat products will help maintaining their quality and safety, it is appropriate to authorise its use in heat-treated meat products and to assign number E 243 to that food additive.

([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]) The EFSA Journal (2007) 511, p. 1.
([5]) EFSA Journal 2013;11(6):3294.

(8) The specifications for Ethyl lauroyl arginate (E 243) should be included in Regulation (EU) No 231/2012 when it is included in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.

(9) Regulations (EC) No 1333/2008 and (EU) No 231/2012 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

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*.

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

Done at Brussels, 15 May 2014.

For the Commission
The President
José Manuel BARROSO

ANNEX I

Annex II to Regulation (EC) No 1333/2008 is amended as follows:

(1) In Part B, point 3 'Additives other than colours and sweeteners', the following new entry is inserted after the entry for 'E 242 Dimethyl dicarbonate':

'E 243	Ethyl lauroyl arginate'

(2) In Part E, in food category 08.2.2 'Heat treated processed meat', the following new entry is inserted:

	'E 243	Ethyl lauroyl arginate	160		Except emulsified sausages, smoked sausages and liver paste'

ANNEX II

In the Annex to Regulation (EU) No 231/2012, the following new entry is inserted after the specifications for food additive E 242:

'E 243 ETHYL LAUROYL ARGINATE

Synonyms	Lauric arginate ethyl ester; lauramide arginine ethyl ester; ethyl-Nα-lauroyl-L-arginate·HCl; LAE;
Definition	Ethyl lauroyl arginate is synthesized by esterifying arginine with ethanol, followed by reacting the ester with lauroyl chloride. The resultant ethyl lauroyl arginate is recovered as the hydrochloride salt, which is filtered and dried.
ELINCS	434-630-6
Chemical name	Ethyl-Nα-dodecanoyl-L-arginate·HCl
Chemical formula	C20H41N4O3Cl
Molecular Weight	421,02
Assay	Not less than 85 % and not more than 95 %
Description	White powder
Identification	
Solubility	Freely soluble in water, ethanol, propylene glycol and glycerol
Purity	
Nα-Lauroyl-L-arginine	Not more than 3 %
Lauric acid	Not more than 5 %
Ethyl laurate	Not more than 3 %
L-Arginine·HCl	Not more than 1 %
Ethyl arginate·2HCl	Not more than 1 %
Lead	Not more than 1 mg/kg
Arsenic	Not more than 3 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg'