Commission Regulation (EU) 2015/537 of 31 March 2015 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of aluminium lakes of cochineal, carminic acid, carmines (E 120) in dietary foods for special medical purposes (Text with EEA relevance)

COMMISSION REGULATION (EU) 2015/537

of 31 March 2015

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of aluminium lakes of cochineal, carminic acid, carmines (E 120) in dietary foods for special medical purposes

(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),

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) The Union list of food additives 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 Council[(2)] either on the initiative of the Commission or following an application.

(3) The European Food Safety Authority ('the Authority'), in its opinion of 22 May 2008[(3)] recommended lowering the tolerable weekly intake (TWI) for aluminium to 1 mg/kg body weight/week. In addition, the Authority considered that the revised TWI was generally exceeded for high consumers, especially children, in a significant part of the Union. In order to ensure that the revised TWI is not exceeded, the conditions of use and the use levels for food additives containing aluminium, including aluminium lakes were amended by Commission Regulation (EU) No 380/2012[(4)].

(4) Regulation (EU) No 380/2012 provides that aluminium lakes prepared from all colours listed in Table 1 of Part B of Annex II to Regulation (EC) No 1333/2008 are authorised until 31 July 2014. From 1 August 2014 only aluminium lakes prepared from the colours listed in Table 3 of Part A of Annex II to Regulation (EC) No 1333/2008 are authorised and only in those food categories where provisions on maximum limits on aluminium coming from lakes are explicitly stated in Part E of that Annex.

(5) An application for the extension of use of aluminium lakes of cochineal, carminic acid, carmines (E 120) in dietary foods for special medical purposes was submitted on 30 October 2013 and has been made available to the Member States pursuant to Article 4

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2015/537. (See end of Document for details)*

of Regulation (EC) No 1331/2008. This application requested to set the maximum level of aluminium coming from aluminium lakes of cochineal, carminic acid, carmines in those foods. The extension of use was requested for dietary foods for special medical purposes which are not intended for infants and young children. While considering the application a special attention was paid to a possible exposure to aluminium in order not to undermine Regulation (EU) No 380/2012.

(6) In aluminium lakes of colours the dye is rendered insoluble and functions differently to its dye equivalent (e.g. improved light, pH and heat stability, preventing colour bleed and providing a different colour shade to dye colours) making the lake form suitable for certain specific technical applications. Aluminium lakes of cochineal, carminic acid, carmines are suitable to meet the technological need of liquid heat-treated dietary foods for special medical purposes.

(7) Dietary foods for special medical purposes are defined by Commission Directive 1999/21/EC[(5)] as a category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two.

(8) Taking into account the consumption data for dietary foods for special medical purposes from the EFSA Comprehensive European Food Consumption Database[(6)] and assuming that they would contain aluminium at the maximum level of 3 mg/kg, the exposure to aluminium from those foods remains well below the TWI — 1 mg/kg body weight/week for both adults and children. Therefore, considering that the exposure to aluminium from other dietary sources would be limited especially in case of the exclusive feeding it is not expected that the TWI would be exceeded for patients consuming dietary foods for special medical purposes.

(9) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is 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 such update is not liable to have an effect on human health. Since the extension of use of aluminium lakes of cochineal, carminic acid, carmines constitute 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) Therefore, Annex II to Regulation (EC) No 1333/2008 should 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:

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2015/537. (See end of Document for details)*

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*.

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

Done at Brussels, 31 March 2015.

For the Commission

The President

Jean-Claude JUNCKER