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To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union

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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 as regards the use of aluminium lakes of riboflavins (E 101) and cochineal, carminic acid, carmines (E 120) in certain food categories and Annex to Regulation (EU) No 231/2012 as regards the specifications for riboflavins (E 101)

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Delegations will find attached document D033636/04.

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**COMMISSION REGULATION (EU) No .../..**

**of **XXX****

**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 riboflavins (E 101) and cochineal, carminic acid, carmines (E 120) in certain food categories and Annex to Regulation (EU) No 231/2012 as regards the specifications for riboflavins (E 101)**

(Text with EEA relevance)

# COMMISSION REGULATION (EU) No .../..

of **XXX**

**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 riboflavins (E 101) and cochineal, carminic acid, carmines (E 120) in certain food categories and Annex to Regulation (EU) No 231/2012 as regards the specifications for riboflavins (E 101)**

(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<sup>1</sup>, and in particular Article 10(3) and Article 14,

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<sup>2</sup> lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (3) The Union list of food additives and the specifications 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 either on the initiative of the Commission or following an application<sup>3</sup>.
- (4) The European Food Safety Authority (hereinafter: 'the Authority'), in its opinion of 22 May 2008<sup>4</sup> recommended to lower 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,

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<sup>1</sup> OJ L 354, 31.12.2008, p. 16.

<sup>2</sup> 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).

<sup>3</sup> 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 (OJ L 354, 31.12.2008, p. 1).

<sup>4</sup> Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (AFC) on Safety of aluminium from dietary intake, (*The EFSA Journal* (2008) 754, p. 1).

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<sup>5</sup>.

- (5) 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.
- (6) Applications for authorisation of the use of aluminium lakes of riboflavins (E 101) and the extension of use of aluminium lakes of cochineal, carminic acid, carmines (E 120) were submitted in the course of 2013 and have been made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008. While considering the applications a special attention was paid to a possible exposure to aluminium in order not to undermine Regulation (EU) No 380/2012.
- (7) 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.
- (8) The authorisation of aluminium lakes of riboflavins provides an alternative to aluminium lakes of other yellow colours in foods in which the use of aluminium lakes is authorised. The use levels requested for aluminium lakes of cochineal, carminic acid, carmines are low and the extension of use is either to niche products or to products which are not consumed by children. A higher use level for pasteurised fish roe is needed due to the heat treatment to guarantee a stable colour during the shelf life of the product. It is not expected that the authorisation of aluminium lakes of riboflavins and the extension of use of aluminium lakes of cochineal, carminic acid, carmines would have a significant impact on the total exposure to aluminium.
- (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 authorisation of aluminium lakes of riboflavins and the extensions of use of aluminium lakes of cochineal, carminic acid, carmines constitute updates of that list which are not liable to have an effect on human health, it is not necessary to seek the opinion of the Authority.
- (10) Annex to Regulation (EU) No 231/2012 stipulates that a colour may be used in the form of aluminium lakes only where explicitly stated. Therefore, the authorisation of aluminium lakes of riboflavins (E 101) requires modification of the specifications for that food additive provided in the Annex to Regulation (EU) No 231/2012 with regard to use of aluminium lakes of colours.

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<sup>5</sup> Commission Regulation (EU) No 380/2012 of 3 May 2012 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the conditions of use and the use levels for aluminium-containing food additives (OJ L 119, 4.5.2012, p. 14).

- (11) Therefore, Annex II to Regulation (EC) No 1333/2008 and Annex to Regulation (EU) No 231/2012 should be amended accordingly.
- (12) 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*

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,

*For the Commission*  
*The President*  
*José Manuel BARROSO*