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 (Text with EEA relevance)

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

(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) 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) The European Food Safety Authority (EFSA), in its opinion of 22 May 2008[(2)] recommended to lower the tolerable weekly intake (TWI) for aluminium to 1 mg/kg body weight/week. In addition, EFSA considers that the revised TWI is generally exceeded for high consumers, especially children, in a significant part of the Union.

(3) EFSA considers that the major route of exposure to aluminium compounds for the general population is through food, both as a consequence of the natural occurrence of aluminium in food and the use of aluminium compounds in food processing, including food additives. However, EFSA is not able to quantify the respective role of each source due to the design of the human dietary studies and the analytical methods used, which only determine the total aluminium content in food.

(4) Annex II to Regulation (EC) No 1333/2008 authorises the use of aluminium-containing food additives in a wide number of foodstuffs, often at very high maximum permitted levels or without any indication of the maximum concentration levels (*Quantum satis*).

(5) Annex II to Regulation (EC) No 1333/2008 and Commission Regulation (EU) No 231/2012 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[(3)] authorise the use of some colours that may contain aluminium in the form of lakes in a wide number of foodstuffs, in general without any indication of the maximum concentration levels of aluminium in the lakes.

(6) It is therefore appropriate to amend the current conditions of use and reduce the use levels for aluminium-containing food additives, including aluminium lakes, to ensure that the revised TWI is not exceeded.

(7) Since manufacturing practices using higher amounts of food additives have been applied since decades, a transitional period should be provided to allow the food business operators to adapt to the new requirements laid down in this Regulation for the uses of aluminium-containing food additives others than lakes.

(8) Labelling of aluminium content in aluminium lakes not intended for sale to the final consumer is currently optional. It should become mandatory within 12 months from the entry into force of this Regulation in order to allow food manufacturers using aluminium lakes to adapt to the proposed maximum limits for such lakes. Therefore a longer transitional period than 12 months should be provided to allow the food business operators to adapt to the new requirements laid down in this Regulation.

(9) Annex II as amended by Commission Regulation (EU) No 1129/2011[(4)] is in principle applicable from 1 June 2013. In order to facilitate the effective implementation of Annex II, it is appropriate to insert in the Annex the periods of application that do not start on 1 June 2013 and are posterior to the entry into force of this Regulation.

(10) The aluminium containing carrier bentonite, E 558 is not used any more according to information submitted by food manufacturers. Therefore, it is not included in Part 1 of Annex III to Regulation (EC) No 1333/2008 and should also be deleted from the list of all additives in Part B of Annex II to Regulation (EC) No 1333/2008.

(11) The aluminium containing food additives calcium aluminium silicate E 556 and aluminium silicate (kaolin) E 559 should be deleted from the list of all additives in Part B of Annex II to Regulation (EC) No 1333/2008, since these substances can be replaced by other food additives.

(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, and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

1 Foods not complying with the provisions laid down in this Regulation applicable from 1 February 2014 that have been lawfully placed on the market before 1 February 2014, may continue to be marketed until their date of minimum durability or use-by date.

2 By derogation from paragraph 1, foods containing aluminium lakes and not complying with the provisions laid down in this Regulation applicable from 1 August 2014, that have been lawfully placed on the market before 1 August 2014, may continue to be marketed until their date of minimum durability or use-by date.

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 the Member States.

Done at Brussels, 3 May 2012.

For the Commission

The President

José Manuel BARROSO

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 380/2012. (See end of Document for details)*

ANNEX

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

(a) Part A is amended as follows:

(i) In Section 2, point 4 is replaced by the following:

4. Aluminium lakes prepared from all colours listed in Table 1 of Part B are authorised until 31 July 2014.

From 1 August 2014 only aluminium lakes prepared from the colours listed in Table 3 of this Part A are authorised and only in those food categories where provisions on maximum limits on aluminium coming from lakes are explicitly stated in Part E .

(ii) the following Table 3 is added:

TABLE 3

Colours which may be used in the form of lakes

E-number	Name
E 100	Curcumin
E 102	Tartrazine
E 104	Quinoline Yellow
E 110	Sunset Yellow FCF/Orange Yellow S
E 120	Cochineal, Carminic acid, Carmines
E 122	Azorubine, Carmoisine
E 123	Amaranth
E 124	Ponceau 4R, Cochineal Red A
E 127	Erythrosine
E 129	Allura Red AC
E 131	Patent Blue V
E 132	Indigotine, Indigo carmine
E 133	Brilliant Blue FCF
E 141	Copper complexes of chlorophylls and chlorophyllins
E 142	Green S
E 151	Brilliant Black BN, Black PN
E 155	Brown HT
E 163	Anthocyanins
E 180	Litholrubine BK

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 380/2012. (See end of Document for details)*

(b) In Part B, Table 3, (Additives other than colours and sweeteners) is amended as follows:

(i) the entries concerning E 556 Calcium aluminium silicate, E 558 Bentonite and E 559 Aluminium silicate (Kaolin) are replaced by the following:

E 556	Calcium aluminium silicate (*)
E 558	Bentonite (**)
E 559	Aluminium silicate (Kaolin) (*)

(ii) the following footnotes are added:

(*) = authorised until 31 January 2014

(**) = authorised until 31 May 2013

(c) In Part C, Table (5), point (s) "E 551 – 559: Silicon dioxide – silicates" is replaced by the following:

(s.1.) E 551 – 559: Silicon dioxide – silicates[(5)]

E-number	**Name**
E 551	Silicon dioxide
E 552	Calcium silicate
E 553a	Magnesium silicate
E 553b	Talc
E 554	Sodium aluminium silicate
E 555	Potassium aluminium silicate
E 556	Calcium aluminium silicate
E 559	Aluminium silicate (Kaolin)

(s.2.) E 551 – 553: Silicon dioxide – silicates[(6)]

E-number	**Name**
E 551	Silicon dioxide
E 552	Calcium silicate
E 553a	Magnesium silicate
E 553b	Talc

(d) Part E is amended as follows:

(1) In category 0 (Food additives permitted in all categories of foods),

(i) the entry concerning additives E 551-559 (only foods in dried powdered form (i.e. foods dried during the production process, and mixtures thereof), excluding foods listed in table 1 of Part A of this Annex) is replaced by the following: