Commission Regulation (EU) No 232/2012 of 16 March 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 Quinoline Yellow (E 104), Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124) (Text with EEA relevance)

COMMISSION REGULATION (EU) No 232/2012

of 16 March 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 Quinoline Yellow (E 104), Sunset Yellow FCF/ Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124)

(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) Quinoline Yellow (E 104), Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124) are food colours currently approved for use and listed in Annex II to Regulation (EC) No 1333/2008. The current approval takes into account the Acceptable Daily Intakes (ADI) established by the Scientific Committee for Food (SCF) in 1983[(2)].

(3) The European Food Safety Authority (hereinafter: 'the Authority') issued an Opinion on 23 September 2009[(3)] related to the re-evaluation on the safety of Quinoline Yellow (E 104) as a food additive. In that Opinion, the Authority recommends to lower the ADI of that food colour from 10 mg/kg bw/day to 0,5 mg/kg bw/day. In addition, the Authority considers that the refined exposure estimates (Tier 2 and Tier 3) are generally well over the revised ADI of 0,5 mg/kg bw/day. It is therefore appropriate to amend the conditions of use and use levels for Quinoline Yellow (E 104) to ensure that the new ADI recommended by the Authority is not exceeded.

(4) The Authority issued an Opinion on 27 September 2009[(4)] related to the re-evaluation on the safety of Sunset Yellow FCF/Orange Yellow S (E 110) as a food additive. In that Opinion, the Authority recommends to lower the ADI for Sunset Yellow FCF/Orange Yellow S (E 110) from 2,5 to 1 mg/kg bw/day. In addition, the Authority considers that the refined exposure estimates (Tier 3) are generally well over the revised temporary ADI of 1 mg/kg bw/day for high-consumer children. It is therefore appropriate to amend

the conditions of use and use levels for Sunset Yellow FCF/Orange Yellow S (E 110) to ensure that the new temporary ADI recommended by the Authority is not exceeded.

(5) The Authority issued an Opinion on 23 September 2009[(5)] related to the re-evaluation on the safety of Ponceau 4R, Cochineal Red A (E 124) as a food additive. In that Opinion, the Authority recommends to lower the ADI from 4 mg/kg bw/day to 0,7 mg/kg bw/day. In addition, the Authority considers that the refined exposure estimates (Tier 3) are generally well over the revised ADI of 0,7 mg/kg bw/day for high-consumer children. It is therefore appropriate to amend the conditions of use and use levels for Ponceau 4R, Cochineal Red A (E 124) to ensure that the new ADI recommended by the authority is not exceeded.

(6) It is necessary to remove these substances from Group III listed in Part C(3) of Annex II. However the combined maximum limit when the substances are used together with the remaining substances belonging to Group III should be maintained.

(7) In order to reduce the exposure below the recommended ADI, maximum limits should be revised. In particular they should be reduced by the same factor as the reduction in daily intake which is aimed at. Certain exceptions with higher levels should be allowed for some traditional products which do not significantly contribute to the exposure. Some provisions have also been deleted.

(8) Annex II to Regulation (EC) No 1333/2008 should therefore be amended accordingly.

(9) In order to allow the necessary time for the food industry to adjust their production to the new conditions of use and the use levels laid down in this Regulation, it is appropriate to provide for transitional arrangements.

(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, 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

This Regulation shall apply from 1 June 2013.

Foods containing Quinoline Yellow (E 104), Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124) that have been lawfully placed on the market before 1 June 2013 but that do not comply with the provisions of this Regulation, may continue to be marketed until stocks are exhausted.

Article 3

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 232/2012. (See end of Document for details)*

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

Done at Brussels, 16 March 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 232/2012. (See end of Document for details)*

ANNEX

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

(1) in Part C, in point (3), the following entries are deleted:

E 104	Quinoline Yellow
‘E 110	Sunset Yellow FCF/Orange yellow S’
‘E 124	Ponceau 4R, Cochineal red A’

(2) Part E is amended as follows:

(a) in the categories 03, 05.2, 05.3, 05.4, 07.2 and 14.1.4 footnote (25) is replaced by the following:

(25): The quantities of each of the colours E 122 and E 155 may not exceed 50 mg/kg or mg/l;

(b) in the category 1.7.5 footnote (33) is replaced by the following:

(33): Maximum individually or for the combination of E 100, E 102, E 120, E 122, E 160e and E 161b;

(c) in the categories 04.2.1, 04.2.2, 04.2.3 and 04.2.4.1 footnote (34) is replaced by the following:

(34): Maximum individually or for the combination of E 120, E 122, E 129, E 131 and E 133;

(d) in the categories 04.2.5.2 and 04.2.5.3 footnote (31) is replaced by the following:

(31): Maximum individually or in combination with E 120, E 142, E 160d and E 161b;

(e) in the category 9.2 footnotes (35), (36) and (37) are replaced by the following:

(35): Maximum individually or for the combination of E 102, E 120, E 122, E 142, E 151, E 160e and E 161b

(36): Maximum individually or for the combination of E 102, E 120, E 122, E 129, E 142, E 151, E 160e and E 161b

(37): Maximum individually or for the combination of E 102, E 120, E 151 and E 160e;

(f) the following entries for E 104, E 110 and E 124 are inserted in numerical order in the food categories referred to:

Category number	**E-Number**	**Name**	**Maximum level(mg/l or mg/kg as appropriate)**	**Footnotes**	**restrictions/ exceptions**

‘**01.4**	**Flavoured fermented milk products including heat treated products**				
	E 104	Quinoline Yellow	10	(61)	
	E 110	Sunset Yellow FCF/ Orange Yellow S	5	(61)	
	E 124	Ponceau 4R, Cochineal Red A	5	(61)	
		(61): The total quantity of E 104, E 110, E 124 and the colours in Group III shall not exceed the maximum listed for Group III			
01.6.3	**Other creams**				
	E 104	Quinoline Yellow	10	(61)	Only flavoured creams
	E 110	Sunset Yellow FCF/ Orange Yellow S	5	(61)	Only flavoured creams
	E 124	Ponceau 4R, Cochineal Red A	5	(61)	Only flavoured creams
		(61): The total quantity of E 104, E 110, E 124 and the colours in Group III shall not exceed the maximum listed for Group III			
01.7.3	**Edible cheese rind**				
	E 104	Quinoline Yellow	10	(62)	
		(62): The total quantity of E 104 and the colours in Group III shall not exceed the maximum listed for Group III			
04.2.4.1	**Fruit and vegetable preparations excluding compote**				
	E 104	Quinoline Yellow	30	(61)	Only *mostarda di frutta*