



EUROPEAN COMMISSION

Brussels, XXX
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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 with regard to conditions of use and use levels of Quinoline Yellow, Sunset Yellow and Ponceau 4R

(Text with EEA relevance)

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

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amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council with regard to conditions of use and use levels of Quinoline Yellow, Sunset Yellow and Ponceau 4R

(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 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, in particular Article 7(5) thereof¹,

After consulting the European Food Safety Authority

Whereas:

- (1) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives² lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) Commission Regulation XXXX amends Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives³.
- (3) Quinoline Yellow (E 104) is a food colour currently authorised under Annex II to Regulation (EC) No 1333/2008. The European Food Safety Authority (hereinafter: 'the Authority') re-evaluated the safety of Quinoline Yellow (E 104) and recommended to lower down its acceptable daily intake (ADI) from 10 mg/kg bw/d to 0.5 mg/kg bw/day in its opinion on 23 September 2009⁴. In addition, the Authority considered 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 reduce the current

¹ OJ L 354, 31.12.2008, p. 1.

² OJ L 354, 31.12.2008, p. 16.

³ [OJ reference to be added]

⁴ Scientific opinion of the Panel on Food Additives and Nutrient sources added to Food (ANS) on a request from the Commission related to the re-evaluation on the safety of Quinoline Yellow (E 104) when used as a food additive, The EFSA Journal 2009; 7(11):1329.

conditions of use and use levels for Quinoline Yellow to ensure that the new ADI is not exceeded any more.

- (4) Sunset Yellow (E 110) is a food colour currently authorised under Annex II to Regulation (EC) No 1333/2008. The Authority re-evaluated the safety of Sunset Yellow⁵. Based on the available scientific data, the Authority considered necessary to reduce the ADI by an extra uncertainty factor of 2.5, leading to 1 mg/kg bw/day and to make the ADI temporary for 2 years, until September 2011. In addition, the Authority considered 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 reduce the current conditions of use and use levels for Sunset Yellow to ensure that the new temporary ADI is not exceeded anymore.
- (5) Ponceau 4R (E 124) is a food colour currently authorised under Annex II to Regulation (EC) No 1333/2008. The Authority re-evaluated the safety of Ponceau 4R and recommended to lower down the ADI from 4 mg/kg bw/d to 0.7 mg/kg bw/d in its opinion⁶ on 23 September 2009. In addition, the Authority considered 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 reduce the current conditions of use and use levels for Ponceau 4R to ensure that the new ADI is not exceeded any more.
- (6) In order to allow the necessary time for the food industry to develop alternatives to these current authorisations, it is necessary to provide for transitional arrangements.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the [...] Committee, 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 by [date of entry into force + 24 months]

⁵ Scientific opinion of the Panel on Food Additives and Nutrient sources added to Food (ANS) on a request from the Commission related to the re-evaluation on the safety of Sunset Yellow (E 110) as a food additive, The EFSA Journal 2009; 7(11):1330.

⁶ Scientific opinion of the Panel on Food Additives and Nutrient sources added to Food (ANS) on a request from the Commission related to the re-evaluation on the safety of Ponceau 4R as a food additive, The EFSA Journal 2009; 7(11):1328.

Foods containing Quinoline Yellow, Sunset Yellow and Ponceau 4R that have been lawfully placed on the market before [date of entry into force + 24 months], but do not comply with this Regulation, may continue to be marketed until stocks are exhausted.

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,

For the Commission
José Manuel BARROSO
The President

ANNEX

ANNEX

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

(1) In Part C (3) Group III: Food colours with combined maximum limit

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) In Part E the following entries for E 104, E 110, E 124 are inserted :

PART E: AUTHORISED FOOD ADDITIVES AND CONDITIONS OF USE IN FOOD CATEGORIES

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	(59)	

	E 110	Sunset Yellow FCF/Orange Yellow S	5	(59)	
	E 124	Ponceau 4R, Cochineal Red A	5	(59)	
		(59): 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	(59)	
	E 110	Sunset Yellow FCF/Orange Yellow S	5	(59)	
	E 124	Ponceau 4R, Cochineal Red A	5	(59)	
		(59): 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	(60)	
		(60): 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			
04.2.4.1	Fruit and vegetable preparations excluding compote				
	E 104	Quinoline Yellow	30	(59)	
	E 110	Sunset Yellow FCF/Orange Yellow S	35	(59)	
	E 124	Ponceau 4R, Cochineal Red A	20	(59)	
		(59): 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			
05.2	Other confectionery including breath refreshing microsweets				
	E 104	Quinoline Yellow	30	(59)	except candied fruit and vegetables; traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc.
	E 110	Sunset Yellow FCF/Orange Yellow S	35	(25) (59)	except candied fruit and vegetables; traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc.
	E 124	Ponceau 4R, Cochineal Red A	20	(25) (59)	except candied fruit and vegetables; traditional sugar coated nut- or

					cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc.
	E 104	Quinoline Yellow	30	(59)	only candied fruit and vegetables
	E 110	Sunset Yellow FCF/Orange Yellow S	10	(59)	only candied fruit and vegetables
	E 124	Ponceau 4R, Cochineal Red A	10	(59)	only candied fruit and vegetables
	E 104	Quinoline Yellow	50	(59)	only traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc.
	E 110	Sunset Yellow FCF/Orange Yellow S	50	(25) (59)	only traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings, communion etc.
	E 124	Ponceau 4R, Cochineal Red A	300	(25) (59)	only traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions ie: weddings , communion etc.
		(25): The quantities of each of the colours E 110, E 122, E 124 and E 155 may not exceed 50 mg/kg or mg/l			
		(59): 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			
05.3	Chewing gum				
	E 104	Quinoline Yellow	30	(59)	
	E 110	Sunset Yellow FCF/Orange Yellow S	10	(25) (59)	
	E 124	Ponceau 4R, Cochineal Red A	10	(25) (59)	
		(25): The quantities of each of the colours E 110, E 122, E 124 and E 155 may not exceed 50 mg/kg or mg/l			
		(59): 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			
05.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4				
	E 104	Quinoline Yellow	50	(59)	only decorations, coatings and sauces, except fillings

	E 110	Sunset Yellow FCF/Orange Yellow S	35	(59)	only decorations, coatings and sauces, except fillings
	E 124	Ponceau 4R, Cochineal Red A	55	(59)	only decorations, coatings and sauces, except fillings
	E 104	Quinoline Yellow	50	(59)	only fillings
	E 110	Sunset Yellow FCF/Orange Yellow S	35	(25) (59)	only fillings
	E 124	Ponceau 4R, Cochineal Red A	55	(25) (59)	only fillings
		(25): The quantities of each of the colours E 110, E 122, E 124 and E 155 may not exceed 50 mg/kg or mg/l			
		(59): 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			
06.6	Batters				
	E 104	Quinoline Yellow	50	(59)	
	E 110	Sunset Yellow FCF/Orange Yellow S	35	(59)	
	E 124	Ponceau 4R, Cochineal Red A	55	(59)	
		(59): 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			
08.2.3	Casings and coatings and decorations for meat				
	E 104	Quinoline Yellow	50	(59)	only decorations and coatings except edible external coating of <i>pasturmas</i>
	E 110	Sunset Yellow FCF/Orange Yellow S	35	(59)	only decorations and coatings except edible external coating of <i>pasturmas</i>
	E 124	Ponceau 4R, Cochineal Red A	55	(59)	only decorations and coatings except edible external coating of <i>pasturmas</i>
	E 104	Quinoline Yellow	10	(59)	only edible casings
		(59): 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			
09.2	Processed fish and fishery products including mollusks and crustaceans				
	E 110	Sunset Yellow FCF/Orange Yellow S	200	(35) (59)	only in salmon substitutes based on <i>Theragra chalcogramma</i> and <i>Pollachius virens</i>
	E 124	Ponceau 4R, Cochineal Red A	55	(59)	only in salmon substitutes based on <i>Theragra chalcogramma</i> and

					<i>Pollachius virens</i>
		(35): Maximum individually or for the combination of E 102, E 104, E 110, E 120, E 122, E 124, E 142, E 151, E 160e, E 161b			
		(37): Maximum individually or for the combination of E 102, E 110, E 120, E 124, E 151, E 160e			
09.3	Fish roe				
	E 104	Quinoline Yellow	200	(59)	except Sturgeons' eggs (Caviar)
	E 110	Sunset Yellow FCF/Orange Yellow S	200	(59)	except Sturgeons' eggs (Caviar)
	E 124	Ponceau 4R, Cochineal Red A	55	(59)	except Sturgeons' eggs (Caviar)
		(59): 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			
12.2.2	Seasonings and condiments				
	E 104	Quinoline Yellow	10	(59)	only seasonings, for example curry powder, tandoori
		(59): 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			
12.4	Mustard				
	E 104	Quinoline Yellow	10	(59)	
	E 110	Sunset Yellow FCF/Orange Yellow S	50	(59)	
	E 124	Ponceau 4R, Cochineal Red A	35	(59)	
		(59): 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			
12.6	Sauces				
	E 104	Quinoline Yellow	20	(59)	including pickles, relishes, chutney and picalilli; excluding tomato-based sauces
	E 110	Sunset Yellow FCF/Orange Yellow S	30	(59)	only in pickles and picalilli
		(59): 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			
12.9	Protein products, excluding products covered in category 1.8				
	E 104	Quinoline Yellow	10	(59)	only meat and fish analogues based on vegetable proteins
	E 110	Sunset Yellow FCF/Orange Yellow S	20	(59)	only meat and fish analogues based on vegetable proteins
	E 124	Ponceau 4R, Cochineal Red A	10	(59)	only meat and fish analogues based on vegetable proteins

				(59): 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	
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)				
	E 104	Quinoline Yellow	10	(59)	
	E 110	Sunset Yellow FCF/Orange Yellow S	10	(59)	
	E 124	Ponceau 4R, Cochineal Red A	10	(59)	
				(59): 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	
13.3	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)				
	E 104	Quinoline Yellow	10	(59)	
	E 110	Sunset Yellow FCF/Orange Yellow S	10	(59)	
	E 124	Ponceau 4R, Cochineal Red A	10	(59)	
				(59): 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	
14.1.4	Flavoured drinks				
	E 104	Quinoline Yellow	10	(59)	excluding chocolate milk and malt products
	E 110	Sunset Yellow FCF/Orange Yellow S	20	(25) (59)	excluding chocolate milk and malt products
	E 124	Ponceau 4R, Cochineal Red A	10	(25) (59)	excluding chocolate milk and malt products
				(25): The quantities of each of the colours E 110, E 122, E 124 and E 155 may not exceed 50 mg/kg or mg/l	
				(59): 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	
14.2.3	Cider and perry				
	E 104	Quinoline Yellow	25	(59)	excluding cidre bouché
	E 110	Sunset Yellow FCF/Orange Yellow S	10	(59)	excluding cidre bouché
				(59): The total quantity of E 104, E 110 and the colours in Group III shall not exceed the maximum listed for Group III	
14.2.4	Fruit wine and made wine				
	E 104	Quinoline Yellow	20	(59)	
	E 110	Sunset Yellow FCF/Orange Yellow S	10	(59)	

	E 124	Ponceau 4R, Cochineal Red A	1	(59)	
		(59): The total quantity of E 124 and the colours in Group III shall not exceed the maximum listed for Group III			
14.2.7.1	Aromatised wines				
	E 104	Quinoline Yellow	50	(59)	Except <i>americano, bitter vino</i>
	E 110	Sunset Yellow FCF/Orange Yellow S	50	(59)	Except <i>americano, bitter vino</i>
	E 124	Ponceau 4R, Cochineal Red A	50	(59)	Except <i>americano, bitter vino</i>
		(59): 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			
14.2.7.2	Aromatised wine-based drinks				
	E 104	Quinoline Yellow	50	(59)	except <i>bitter soda, sangria, claria, zurra</i>
	E 110	Sunset Yellow FCF/Orange Yellow S	50	(59)	except <i>bitter soda, sangria, claria, zurra</i>
	E 124	Ponceau 4R, Cochineal Red A	50	(59)	except <i>bitter soda, sangria, claria, zurra</i>
		(59): 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			
14.2.7.3	Aromatised wine-product cocktails				
	E 104	Quinoline Yellow	50	(59)	
	E 110	Sunset Yellow FCF/Orange Yellow S	50	(59)	
	E 124	Ponceau 4R, Cochineal Red A	50	(59)	
		(59): 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			
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol				
	E 104	Quinoline Yellow	180	(59)	only alcoholic drinks with less than 15 % of alcohol
	E 110	Sunset Yellow FCF/Orange Yellow S	100	(59)	only alcoholic drinks with less than 15 % of alcohol
	E 124	Ponceau 4R, Cochineal Red A	170	(59)	only alcoholic drinks with less than 15 % of alcohol
		(59): 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			
16.	Desserts excluding products covered in category 1, 3 and 4				
	E 104	Quinoline Yellow	10	(59)	

	E 110	Sunset Yellow FCF/Orange Yellow S	5	(59)	
	E 124	Ponceau 4R, Cochineal Red A	10	(59)	
		(59): 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			
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms				
	E 104	Quinoline Yellow	35	(59)	
	E 110	Sunset Yellow FCF/Orange Yellow S	10	(59)	
	E 124	Ponceau 4R, Cochineal Red A	35	(59)	
		(59): 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			
17.2	Food supplements supplied in a liquid form				
	E 104	Quinoline Yellow	10	(59)	
	E 110	Sunset Yellow FCF/Orange Yellow S	10	(59)	
	E 124	Ponceau 4R, Cochineal Red A	10	(59)	
		(59): 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			
17.3	Food supplements supplied in a syrup-type or chewable form				
	E 104	Quinoline Yellow	10	(59)	
	E 110	Sunset Yellow FCF/Orange Yellow S	10	(59)	
	E 124	Ponceau 4R, Cochineal Red A	10	(59)	
		(59): 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			

(3) In Part E the current entries for E 104, E 110, E 124 are replaced by the following:

08.2.1	Non heat treated processed meat				
	E 110	Sunset yellow FCF/Orange Yellow S	15		only <i>sobrasada</i>

	E 124	Ponceau 4R, Cochineal Red A	50		only <i>chorizo sausage/salchichon</i>
14.2.7.1	Aromatised wines				
	E 104	Quinoline Yellow	50	(26) (27)	only <i>americano, bitter vino</i>
	E 110	Sunset Yellow FCF/Orange Yellow S	50	(27)	only <i>bitter vino</i>
	E 124	Ponceau 4R, Cochineal Red A	50	(26) (27)	only <i>americano, bitter vino</i>
14.2.7.2	Aromatised wine-based drinks				
	E 104	Quinoline Yellow	50	(28)	only <i>bitter soda</i>
	E 110	Sunset Yellow FCF/Orange Yellow S	50	(28)	only <i>bitter soda</i>
	E 124	Ponceau 4R, Cochineal Red A	50	(28)	only <i>bitter soda</i>

(4) In Part E the following entries for E 104, E 110, E 124 are deleted:

01.7.5	Processed cheese				
	E 104	Quinoline Yellow	100	(33)	only flavoured processed cheese
	E 110	Sunset Yellow FCF/Orange Yellow S	100	(33)	only flavoured processed cheese
	E 124	Ponceau 4R, Cochineal Red A	100	(33)	only flavoured processed cheese
04.2.1	Dried fruit and vegetables				
	E 124	Ponceau 4R, Cochineal Red A	200	(34)	only preserves of red fruit
04.2.2	Fruit and vegetables in vinegar, oil, or brine				
	E 124	Ponceau 4R, Cochineal Red A	200	(34)	only preserves of red fruit
04.2.3	Canned or bottled fruit and vegetables				
	E 124	Ponceau 4R, Cochineal Red A	200	(34)	only preserves of red fruit
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EC				
	E 104	Quinoline Yellow	100	(31)	except chestnut puree
	E 110	Sunset Yellow FCF/Orange Yellow S	100	(31)	except chestnut puree

	E 124	Ponceau 4R, Cochineal Red A	100	(31)	except chestnut puree
04.2.5.3	Other similar fruit or vegetable spreads				
	E 104	Quinoline Yellow	100	(31)	except chestnut puree
	E 110	Sunset Yellow FCF/Orange Yellow S	100	(31)	except chestnut puree
	E 124	Ponceau 4R, Cochineal Red A	100	(31)	except chestnut puree
08.2.1	Non heat treated processed meat				
	E 124	Ponceau 4R, Cochineal Red A	200		only <i>sobrasada</i>
09.2	Processed fish and fishery products including mollusks and crustaceans				
	E 104	Quinoline Yellow	100	(35)	only fish paste and crustacean paste
	E 110	Sunset Yellow FCF/Orange Yellow S	100	(35)	only fish paste and crustacean paste
	E 124	Ponceau 4R, Cochineal Red A	100	(35)	only fish paste and crustacean paste
	E 110	Sunset Yellow FCF/Orange Yellow S	250	(36)	only precooked crustacean
	E 124	Ponceau 4R, Cochineal Red A	250	(36)	only precooked crustacean
	E 110	Sunset Yellow FCF/Orange Yellow S	100	(37)	only smoked fish
	E 124	Ponceau 4R, Cochineal Red A	100	(37)	only smoked fish