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.
- 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.
- 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*.

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

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:
 - 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;
 - 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 appropriat		restrictions/ exceptions
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'01.4	Flavoure treated p	d fermented i	nilk prod	lucts includi	ng heat		
	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 110 124 and the colours in Group III s 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		
		12 no	(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 ch	neese rind					
	E 104	Quinoline Yellow	10	(62)			
		co	(62): The total quantity of E 104 and the colours in Group III shall not exceed the maximum listed for Group III				
	-	nd vegetable preparations excluding compote					

E 104	Quinoline Yellow	30	(61)	Only mostarda di frutta
E 110	Sunset Yellow FCF/ Orange Yellow S	35	(61)	Only mostarda di frutta
E 124	Ponceau 4R, Cochineal Red A	20	(61)	Only mostarda di frutta
	12 no	he total quan 24 and the co ot exceed the roup III	olours in Gro	oup III shall
0.1	· · ·	1 11 1	41 6 1	•

05.2 Other confectionery including breath refreshening microsweets

E 104	Quinoline Yellow	30	(61)	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, i.e. weddings, communion, etc.
E 110	Sunset Yellow FCF/	35	(61)	except candied fruit and vegetables;

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	Orange Yellow S			traditional sugar coated nut- or cocoabased confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions, i.e. weddings, communion, etc.
E 124	Ponceau 4R, Cochineal Red A	20	(61)	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, i.e. weddings, communion, etc.
E 104	Quinoline Yellow	30	(61)	only candied

				fruit and vegetables
E 110	Sunset Yellow FCF/ Orange Yellow S	10	(61)	only candied fruit and vegetables
E 124	Ponceau 4R, Cochineal Red A	10	(61)	only candied fruit and vegetables
E 104	Quinoline Yellow	300	(61)	only traditional sugar coated nut- or cocoabased confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions, i.e. weddings, communion, etc.
E 110	Sunset Yellow FCF/ Orange Yellow S	50	(61)	only traditional sugar coated nut- or cocoabased confectionery of almond shape or host shape, typically longer than 2 cm and typically

05.3

				consumed at celebratory occasions, i.e. weddings, communion, etc.
E 124	12	4 and the co	tity of E 104,	ıp III shall
	Gı	t exceed the oup III	maximum li	sted for
Chewing gi	um			
E 104	Quinoline Yellow	30	(61)	
E 110	Sunset Yellow FCF/ Orange Yellow S	10	(61)	
E 124	Ponceau 4R, Cochineal Red A	10	(61)	

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	1						
		(61): The total quantity of E 104, E 110, 124 and the colours in Group III sh not exceed the maximum listed for Group III					
05.4		ons, coatings a overed by cate			uit based		
	E 104	Quinoline Yellow	50	(61)	only decorations, coatings and sauces, except fillings		
	E 110	Sunset Yellow FCF/ Orange Yellow S	35	(61)	only decorations, coatings and sauces, except fillings		
	E 124	Ponceau 4R, Cochineal Red A	55	(61)	only decorations, coatings and sauces, except fillings		
	E 104	Quinoline Yellow	50	(61)	only fillings		
	E 110	Sunset Yellow FCF/ Orange Yellow S	35	(61)	only fillings		
	E 124	Ponceau 4R, Cochineal Red A	55	(61)	only fillings		
		12 no	(61): The total quantity of E 104, E 110, E 124 and the colours in Group III shal not exceed the maximum listed for Group III				
06.6	Batters	,					
	E 104	Quinoline Yellow	50	(61)			

	E 110	12 nc	35 55 ne total quant 4 and the copt exceed the roup III	lours in Grou	ıp III shall
08.2.3	Casings an		nd decoration	ons for meat	<u> </u>
08.2.3	E 104	Quinoline Yellow	50	(61)	only decorations and coatings except edible external coating of pasturmas
	E 110	Sunset Yellow FCF/ Orange Yellow S	35	(61)	only decorations and coatings except edible external coating of pasturmas
	E 124	Ponceau 4R, Cochineal Red A	55	(61)	only decorations and coatings except edible external coating of pasturmas
	E 104	Quinoline Yellow	10	(62)	only edible casings
			ne total quant 24 and the co		

			not exceed the maximum listed for Group III (62): The total quantity of E 104 and the colours in Group III shall not exceed the maximum listed for Group III				
		co					
09.2	Processe and crus	d fish and fish taceans	ery prod	ucts includi	ng molluscs		
	E 110	Sunset Yellow FCF/ Orange Yellow S	200	(63)	only in salmon substitutes based on Theragra chalcogramm and Pollachius virens		
	E 124	Ponceau 4R, Cochineal Red A	200	(63)	only in salmon substitutes based on Theragra chalcogramm and Pollachius virens		
		ar ex	(63): The total quantity of E 110, E 124 and the colours in Group III shall not exceed the maximum listed for Group III				
09.3	Fish roe	Fish roe					
	E 104	Quinoline Yellow	200	(61)	except Sturgeons' eggs (Caviar)		
	E 110	Sunset Yellow FCF/ Orange Yellow S	200	(61)	except Sturgeons' eggs (Caviar)		
	E 124	Ponceau 4R, Cochineal Red A	200	(61)	except Sturgeons' eggs (Caviar)		
					104, E 110, E Group III shall		

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			ot exceed roup III	I the maximur	n listed for		
12.2.2	Seasonin	gs and condin	nents				
	E 104	Quinoline Yellow	10	(62)	only seasonings, for example curry powder, tandoori		
		co	olours in	quantity of E 1 Group III sha num listed for	ll not exceed		
12.4	Mustard						
	E 104	Quinoline Yellow	10	(61)			
	E 110	Sunset Yellow FCF/ Orange Yellow S	50	(61)			
	E 124	Ponceau 4R, Cochineal Red A	35	(61)			
		(61): The total quantity of E 104, E 11 124 and the colours in Group III not exceed the maximum listed Group III					
12.6	Sauces						
	E 104	Quinoline Yellow	20	(64)	including pickles, relishes, chutney and piccalilli; excluding tomatobased sauces		
	E 110	Sunset Yellow FCF/ Orange Yellow S	30	(64)	only in pickles and piccalilli		

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		aı	nd the col	lours in Grou	104 and E 110 p III shall not sted for Group		
12.9	Protein p	oroducts, excl	uding pr	oducts cover	ed in category		
	E 104	Quinoline Yellow	10	(61)	only meat and fish analogues based on vegetable proteins		
	E 110	Sunset Yellow FCF/ Orange Yellow S	20	(61)	only meat and fish analogues based on vegetable proteins		
	E 124	Ponceau 4R, Cochineal Red A	10	(61)	only meat and fish analogues based on vegetable proteins		
		12 no	24 and th	quantity of E 1 e colours in C the maximur	Group III shall		
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	(61)			
	E 110	Sunset Yellow FCF/ Orange Yellow S	10	(61)			
	E 124	Ponceau 4R, Cochineal Red A	10	(61)			
				uantity of E 1 e colours in C	104, E 110, E Group III shall		

			ot exceed roup III	I the maximur	n listed for			
13.3	total dail	foods for weig ly food intake of the total dai	or an in		ded to replace l (the whole			
	E 104	Quinoline Yellow	10	(61)				
	E 110	Sunset Yellow FCF/ Orange Yellow S	10	(61)				
	E 124	Ponceau 4R, Cochineal Red A	10	(61)				
		12 no	(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					
14.1.4	Flavoured drinks							
	E 104	Quinoline Yellow	10	(61)	excluding chocolate milk and malt products			
	E 110	Sunset Yellow FCF/ Orange Yellow S	20	(61)	excluding chocolate milk and malt products			
	E 124	Ponceau 4R, Cochineal Red A	10	(61)	excluding chocolate milk and malt products			
		12 no	24 and th	quantity of E 1 e colours in Cl the maximum	Group III shall			
14.2.3	Cider an	d perry						
	E 104	Quinoline Yellow	25	(64)	excluding cidre bouché			

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	E 110	Sunset Yellow FCF/ Orange Yellow S	10	(64)	excluding cidre bouché		
		aı	nd the col		104, E 110 p III shall not sted for Group		
14.2.4	Fruit wir	ne and made v	vine				
	E 104	Quinoline Yellow	20	(61)			
	E 110	Sunset Yellow FCF/ Orange Yellow S	10	(61)			
	E 124	Ponceau 4R, Cochineal Red A	1	(61)			
		12 no	24 and th	quantity of E is e colours in C the maximum	Group III shall		
14.2.7.1	Aromatised wines						
	E 104	Quinoline Yellow	50	(61)	Except americano, bitter vino		
	E 110	Sunset Yellow FCF/ Orange Yellow S	50	(61)	Except americano, bitter vino		
	E 124	Ponceau 4R, Cochineal Red A	50	(61)	Except americano, bitter vino		
		12 no	(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				
14.2.7.2	Aromatis	sed wine-base					

	E 104 E 110	Quinoline Yellow Sunset	50	(61)	except bitter soda, sangria, claria, zurra except			
		Yellow FCF/ Orange Yellow S		(01)	bitter soda, sangria, claria, zurra			
	E 124	Ponceau 4R, Cochineal Red A	50	(61)	except bitter soda, sangria, claria, zurra			
		(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						
14.2.7.3	Aromatised wine-product cocktails							
	E 104	Quinoline Yellow	50	(61)				
	E 110	Sunset Yellow FCF/ Orange Yellow S	50	(61)				
	E 124	Ponceau 4R, Cochineal Red A	50	(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						
14.2.8		holic drinks non-alcoho of alcohol						
	E 104	Quinoline Yellow	180	(61)	only alcoholic drinks with less			

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					than 15 % of alcohol			
	E 110	Sunset Yellow FCF/ Orange Yellow S	100	(61)	only alcoholic drinks with less than 15 % of alcohol			
	E 124	Ponceau 4R, Cochineal Red A	170	(61)	only alcoholic drinks with less than 15 % of alcohol			
		(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						
16.	Desserts excluding products covered in categories 1, 3 and 4							
	E 104	Quinoline Yellow	10	(61)				
	E 110	Sunset Yellow FCF/ Orange Yellow S	5	(61)				
	E 124	Ponceau 4R, Cochineal Red A	10	(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						
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms							
	E 104	Quinoline Yellow	35	(61)				
	E 110	Sunset Yellow FCF/ Orange Yellow S	10	(61)				

	E 124	Ponceau 4R, Cochineal Red A	35	(61)			
		12 no	24 and the	uantity of E 1 e colours in G the maximum	roup III shall		
17.2	Food sup	plements sup	plied in a	ı liquid form			
	E 104	Quinoline Yellow	10	(61)			
	E 110	Sunset Yellow FCF/ Orange Yellow S	10	(61)			
	E 124	Ponceau 4R, Cochineal Red A	10	(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					
17.3	Food supplements supplied in a syrup-type or chewable form						
	E 104	Quinoline Yellow	10	(61)			
	E 110	Sunset Yellow FCF/ Orange Yellow S	10	(61)			
	E 124	Ponceau 4R, Cochineal Red A	10	(61)			
		12 no					

⁽g) category 08.2.1 is amended as follows:

⁽i) the entry for E 110 is replaced by the following:

E 110	Sunset yellow FCF/ Orange Yellow S	15	only sobrasada
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(ii) the entry for E 124 is replaced by the following:

E 124	Ponceau	50	only
	Cochineal		chorizo sausage/
	Red A		salchichon

- (h) category 14.2.7.1 is amended as follows:
 - (i) the entries for E 104 and E 110 are replaced by the following:

E 104	Quinoline Yellow	50	(26) (27)	only americano, bitter vino
E 110	Sunset Yellow FCF/ Orange Yellow S	50	(27)	only bitter vino

(ii) the entry for E 124 is replaced by the following:

E 124	Ponceau	50	(26) (27)	
	Cochineal			americano, bitter
	Red A			vino

- (i) category 14.2.7.2 is amended as follows:
 - (i) the entries for E 104 and E 110 are replaced by the following:

E 104	Quinoline Yellow	50	(28)	only bitter soda
E 110	Sunset Yellow FCF/ Orange Yellow S	50	(28)	only bitter soda

(ii) the entry for E 124 is replaced by the following:

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E 124	Ponceau 4R, Cochineal Red A	50	(28)	only bitter soda
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(j) the following entries for E 104, E 110 and E 124 are deleted in the food categories referred to:

01.7.5	Processe	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			
04.2.4.1	Fruit and vegetable preparations excluding compote							
	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							

			1				
	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 crème de pruneaux		
	E 110	Sunset Yellow FCF/ Orange Yellow S	100	(31)	except crème de pruneaux		
	E 124	Ponceau 4R, Cochineal Red A	100	(31)	except crème de pruneaux		
08.2.1	Non heat treated processed meat						
	E 124	Ponceau 4R, Cochineal Red A	200		only sobrasada		
09.2	Processed fish and fishery products including molluscs 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		

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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

- **(1)** OJ L 354, 31.12.2008, p. 16.
- (2) Reports of the Scientific Committee for Food, Fourteenth series, 1983.
- (3) 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.
- (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 Sunset Yellow (E 110) as a food additive, The EFSA Journal 2009; 7(11):1330.
- (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 Ponceau 4R as a food additive, The EFSA Journal 2009; 7(11):1328.

Changes to legislation:

There are currently no known outstanding effects for the Commission Regulation (EU) No 232/2012.