STATEMENT OF EFSA

Refined exposure assessment for Ponceau 4R (E 124)[1]

European Food Safety Authority[2,3]

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ABSTRACT

Following a self-tasking request, the European Food Safety Authority (EFSA) carried out a refined exposure assessment for Ponceau 4R (E 124) taking into account additional information on its use in foods. In 2009, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) adopted a scientific opinion on the re-evaluation of Ponceau 4R (E 124) used as a food additive. In that opinion, the Panel concluded that, at the maximum levels of use, intake estimates for adults at the high percentile (97.5th) and for 1- to 10-year old children at the mean and high percentiles (95th/97.5th) were generally above the Acceptable Daily Intake (ADI), even for the refined intake estimates. Consequently, Annex II to Regulation (EC) No 1333/2008 was amended by the European Commission regarding the conditions of use of Ponceau 4R (E 124), applicable as from 1 June 2013. Many Maximum Permitted Levels (MPLs) of Ponceau 4R (E 124) were withdrawn (n = 24) or decreased by a factor 1.2 to 200 (n = 29), depending on the food category. Following this, EFSA performed a refined exposure assessment for this food colour, using new usage data from industry, as well as analytical data submitted to EFSA by Member States, combined with food consumption data of the EFSA Comprehensive European Food Consumption Database. Usage data from industry were provided for three out of the 31 food categories for which Ponceau 4R (E 124) is authorised as a food additive; while analytical data from Member States were provided to EFSA for 18 food categories. Using MPLs and these new data, none of the exposure estimates exceeded the ADI of 0.7 mg/kg bw per day in any population.

KEY WORDS

Ponceau 4R, E 124, dietary exposure, EFSA Comprehensive European Food Consumption Database, food colours

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SUMMARY

Following an internal mandate proposed by the European Food Safety Authority (EFSA) to the Food Ingredients and Packaging (FIP) Unit for producing EFSA statements with refined exposure calculations for food colours that may possibly exceed the Acceptable Daily Intake (ADI), EFSA carried out a refined exposure assessment for Ponceau 4R (E 124), taking into account additional information on its use in foods and beverages.

Ponceau 4R (E 124) is an azo dye authorised for use as a food additive in the European Union (EU). This food colour has been previously evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1983 and the Scientific Committee for Food (SCF) in 1984. Both committees established an ADI of 0-4 mg/kg body weight (bw) per day.

In 2009, the ANS Panel re-evaluated Ponceau 4R (E 124) as a food additive. The safety of using Ponceau 4R (E 124) was assessed on the basis of uses and use levels authorised in the legislation[4] and of reported use levels, as provided by industry. The ANS Panel derived an ADI of 0.7 mg/kg bw per day, based on the lowest No Observed Adverse Effect Level (NOAEL) derived from a long-term mouse study.

The ANS Panel concluded that, at the maximum levels of use, intake estimates for adults at the high percentile (97.5th) and for 1- to 10-year old children at the mean and high percentiles (95th/97.5th) were generally above the ADI of 0.7 mg/kg bw per day even in the refined intake estimates. Following the conclusions of that opinion, Annex II to Regulation (EC) No 1333/2008 was amended by the European Commission (EC) regarding the conditions of use of Ponceau 4R (E 124) as a food additive applicable from 1 June 2013 onwards (Commission Regulation (EU) No 232/2012)[5]. Many Maximum Permitted Levels (MPLs) were withdrawn (n = 24), or were decreased by a factor 1.2 to 200 (n = 29), depending on the food category.

The present review provides a refined exposure assessment for Ponceau 4R (E 124) based on individual food consumption data from the EFSA Comprehensive European Food Consumption Database, current MPLs and newly submitted information on actual usage levels and analytical data of Ponceau 4R (E 124) in foods as consumed, provided to EFSA by the food industry and Member States respectively, following an EFSA call for data[6] launched in March 2013. Three exposure scenarios were considered: (1) a scenario based on MPLs (*regulatory maximum level exposure assessment*—MPL scenario), (2) a 'brand-loyal exposure' scenario assuming long-term exposure to Ponceau 4R (E 124) at the maximum reported analytical level for one food category and mean analytical levels for other food categories and (3) a 'non-brand-loyal exposure' scenario assuming a long-term exposure to Ponceau 4R (E 124) at the mean reported analytical levels for all foods. The last two scenarios are the so-called *refined exposure assessment* scenarios.

Usage levels of Ponceau 4R (E 124) reported by industry covered three out of the 31 authorised uses of Ponceau 4R (E 124) as a food additive, while analytical data from Member States covered 18 food categories.

The exposure estimates derived from the *regulatory maximum level exposure assessment* scenario were below the ADI of 0.7 mg/kg bw per day for all population groups, at both the mean and the high level (95th percentile). The highest mean dietary exposure to Ponceau 4R (E 124) was observed in

[4] European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs. OJ L 237, 10.9.1994, p. 13.

[5] 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). OJ L 78, 17.03.2012, p. 12.

[6] Call for food additives usage level and/or concentration data in food and beverages intended for human consumption. Published: 27 March 2013. Deadline 15 September 2013. http://www.efsa.europa.eu/en/data/call/130327.htm

toddlers (up to 0.23 mg/kg bw per day), and the highest 95th percentile exposures were observed in toddlers and children (up to 0.51 mg/kg bw per day).

In the refined exposure scenarios both mean and high level exposures to Ponceau R (E 124) were also below the ADI in all population groups. The highest mean dietary exposure to Ponceau 4R (E 124) for the brand-loyal and non-brand-loyal scenarios was observed in toddlers with values of up to 0.20 and 0.16 mg/kg bw/day, respectively; the highest 95th percentile exposure was also observed in toddlers for these scenarios, with values of up to 0.46 and 0.38 mg/kg bw/day, respectively.

For the *regulatory maximum level exposure assessment* scenario, the mean and the 95th percentile exposure estimates of the current exposure assessment of Ponceau 4R (E 124) were much lower than those reported in the evaluation of 2009. In addition, for the refined exposure scenarios, the current exposure estimates for Ponceau 4R (E 124) based on usage data and analytical levels were also lower than those reported in the previous assessment. These differences are the result of the lower MPLs from 2012 onwards, differences in approaches used to include use and analytical data in the exposure assessment, differences in concentration data submitted, availability of more food consumption data and a detailed nomenclature of foods categories, thus allowing a detailed selection of foods that could contain Ponceau 4R (E 124).

EFSA concluded that, considering the *regulatory maximum level exposure assessment* and the refined exposure scenarios, the mean and high-level exposure estimates of Ponceau 4R (E 124) were below the ADI for all population groups.

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Introduction

1.1. Background and Terms of reference as provided by EFSA

In its letter of 26 May 2011 to the European Food Safety Authority (EFSA), the European Commission (EC) requested clarification on the outcomes of the exposure calculations undertaken by the ANS Panel in the opinions on the so-called Southampton colours (quinoline yellow,[7] sunset yellow,[8] ponceau 4R[9]). The Member States and stakeholders had informed the EC that the figures used in these exposure assessments required possibly some updating.

On 1 August 2011, EFSA responded by a letter indicating that following the discussions which took place on 27 May 2011 between EFSA, the EC and Member States representatives, where the possibility to perform refined exposure assessments in the future was discussed, further exchanges between the EC and EFSA have shown an interest for performing such refined assessments.

Once the necessary preparatory work to enable the realisation of the foreseen refined exposure assessments, e.g. the establishment of a correspondence table between the food classification system (FCS) of the new European legislation (Regulation (EU) No 1129/2011[10]) and that of the EFSA Comprehensive Food Consumption Database (FoodEx) had been finalised, EFSA requested information on the priorities set by the EC in its letter of 26 April 2012.

On 23 May 2012, the EC sent a letter to EFSA setting the priorities for the refined exposure assessments of 12 food colours (Priority 1: caramel colours (E 150a, E 150c and E 150d); Priority 2: curcumin (E 100), amaranth (E 123), brown HT (E 155); Priority 3: azorubine/carmoisine (E 122), Ponceau 4R (E 124), brilliant black BN (E 151); Priority 4: quinoline yellow (E 104), sunset yellow (E 110), and ponceau 4R (E 124)), and indicated that revised data on use and use levels for food colours under priorities 2 and 3 were currently being collected by FoodDrinkEurope and should be provided to EFSA once they were available. Similar revised use data for the caramel colours (E 150a, E 150c and E 150d) have been provided by the EC to EFSA.

EFSA is to provide refined exposure assessments for food colours already re-evaluated taking into account the restrictions/exceptions listed in Regulation (EU) No 1129/2011, especially in the case of main contributors.

Furthermore, it is requested that following the establishment of a correspondence table between the FCS of Regulation (EU) No 1129/2011 and that of the EFSA Comprehensive Food Consumption Database (FoodEx), EFSA will use the FoodEx food classification system in order to provide refined exposure assessments and exclude non-relevant food subgroups from the intake calculations. The list of priorities, as provided by the EC, is set as follows:

Priority 1 – caramel colours (E 150a, E 150c, E 150d)

Priority 2 – curcumin (E 100), amaranth (E 123), brown HT (E 155)

Priority 3 – azorubine/carmoisine (E 122), Ponceau 4R (E 124), brilliant black BN (E 151)

Priority 4 – quinoline yellow (E 104), sunset yellow (E 110), ponceau 4R (E 124)

[7] EFSA, 2009. Scientific Opinion on the re-evaluation of Quinoline Yellow (E 104) as a food additive, ON-1329.
[8] EFSA, 2009. Scientific Opinion on the re-evaluation of Sunset Yellow FCF (E 110) as a food additive, ON-1330.
[9] EFSA, 2009. Scientific Opinion on the re-evaluation of Ponceau 4R (E 124) as a food additive, ON-1328.
[10] OJ L 295, 12.11.2011, p.1.

1.2. Interpretation of the Terms of Reference

The aim of the present assessment is to provide a refined exposure assessment for Ponceau 4R (E 124) from its use as a food colour using the approach adopted by the Panel at its 52nd plenary meeting[11] to be followed for the exposure assessment procedure as part of the safety assessment of food additives under re-evaluation. The current exposure assessment therefore uses the EFSA Comprehensive European Food Consumption Database (hereinafter referred as Comprehensive database) and the FoodEx food classification system and takes into consideration, besides the maximum permitted levels (MPLs), updated use levels reported by the industry and analytical data from Member States.

1.3. Additional information

Ponceau 4R (E 124) is an azo dye authorised as a food additive in the EU. This food colour has been previously evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1983 (JECFA, 1983) and the Scientific Committee for Food (SCF) in 1984 (SCF, 1984). Both committees established an Acceptable Daily Intake (ADI) of 0-4 mg/kg body weight (bw) per day.

In 2009, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) re-evaluated Ponceau 4R (E 124) as a food additive (EFSA ANS Panel, 2009). The safety of the use of Ponceau 4R (E 124) was assessed on the basis of MPLs authorised in the legislation[12] and of reported use levels, as provided by industry. The ANS Panel concluded that the overall findings gave reason for the re-definition of the ADI to 0.7 mg/kg bw per day based on a No-Observed-Adverse-Effect Level (NOAEL) from a long-term mouse study.

The ANS Panel concluded that, at the maximum levels of use of Ponceau 4R (E 124), intake estimates for adults at the high percentile (97.5th), and for children at the mean and high percentiles (95th/97.5th) were generally above the ADI, even in the refined intake estimates. The main contributors (> 10 %) to the total anticipated mean exposure of the adult population to Ponceau 4R (E 124) were non-alcoholic beverages (52 %). For children, the main contributing food categories were non-alcoholic beverages (11 to 66 %), desserts, including flavoured milk products (10 to 53 %) and sauces, seasonings (e.g. curry powder, tandoori), pickles, relishes, chutney and piccalilli (11 to 70 %).

Table 1 presents the dietary exposure to Ponceau 4R (E 124) as estimated by the ANS Panel in 2009 for two population groups: children and adults (EFSA ANS Panel, 2009).

Table 1: Summary of anticipated exposure to Ponceau 4R in children and the adult population as calculated in the 2009 ANS Panel opinion (EFSA ANS Panel, 2009) (mg/kg bw per day)

	UK, adults [(a)] (> 18 years old)	**UK [(a)] and EXPOCHI [(b)], children** (1–10 years old, 15–30 kg body weight [(c)])
Estimated exposure using MPLs		
• Mean exposure	0.5	0.3–2.5
• Exposure 95th [(b)] or 97.5th percentile [(a)]	1.1	0.6–6.7
Estimated exposure using reported use levels		
• Mean exposure	0.4	0.3–2.4
• Exposure 95th [(b)] or 97.5th percentile [(a)]	1.0	0.7–6.2

(a): For the UK, estimates are based on the UNESDA (Union of European Soft Drinks Associations) report, which gives the 97.5th percentile intake from beverages plus per capita average from the rest of the diet (Tennant, 2006).
(b): For EU children, estimates are based on the EXPOCHI (individual food consumption data and exposure assessment studies for children) report (Huybrechts et al, 2010), which gives the 95th percentile intake.
(c): For the Cypriot children, the reported body weight was 54 kg for 11- to 14-year-old children.

[11] http://www.efsa.europa.eu/en/events/event/140701a-m.pdf
[12] European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs. OJ L 237, 10.9.1994, p. 13.

A recent German study (Diouf et al., 2014) estimated Ponceau 4R (E 124) intake for toddlers (0.5 to <5 years old) and children (6-11 years old) according to two exposure scenarios. Results showed that the dietary exposure to the food additive was in the range of 0.3 mg/kg bw per day (mean) to 2.6 mg/kg bw per day (high level consumers) for toddlers, and in the range of 0.2 mg/kg bw per day (mean) to 2.3 mg/kg bw per day (high level consumers) for children (6-11 years old).

2. Data and methodologies

2.1. Data

2.1.1. Uses and use levels of Ponceau 4R (E 124)

Maximum permitted levels (MPLs) of use for Ponceau 4R (E 124) are defined in Annex II to Regulation (EC) No 1333/2008[13] on food additives. It is an authorised food colour in the EU, with MPLs ranging from 5 to 200 mg/kg in foods.

Ponceau 4R (E 124) may also be used in the form of colour lakes. Exposure through lakes was not included in the assessment and may have resulted in an underestimation of the total exposure.

It should be noted that in 2012, following the conclusions of the EFSA opinion on Ponceau 4R (E 124) adopted in 2009 by the ANS Panel, Annex II to Regulation (EC) No 1333/2008 was amended regarding the conditions of use and the use levels for Sunset Yellow FCF (E 110), Quinoline Yellow (E 104) and Ponceau 4R (E 124) (Commission Regulation (EU) No 232/2012[14]). For Ponceau 4R (E 124), many MPLs were withdrawn (n = 24) or decreased by a factor 1.2 to 200 (n = 29), depending on the food category, applicable from 1 June 2013 onwards. The MPLs listed in Annex II are shown in Table 2.

Table 2: Maximum permitted levels (MPLs) of Ponceau 4R (E 124) in foods according to Annex II of Regulation (EC) No 1333/2008, as well as the previous MPLs as used in the 2009 EFSA ANS opinion

FCS[(a)] category number	FCS Food category	Restrictions / exception	MPL (mg/L or mg/kg as appropriate)	Previous MPL used in the EFSA ANS opinion (2009) (mg/L or mg/kg as appropriate)
01.4	Flavoured fermented milk products including heat treated products		5 [(b) (c)]	150
01.6.3	Other creams	only flavoured creams	5 [(b)]	150
01.7.1	Unripened cheese excluding products falling in category 16	only flavoured unripened cheese	-	150
01.7.3	Edible cheese rind		-	QS
01.7.5	Processed cheese	only flavoured processed cheese	-	100
01.7.6	Cheese products (excluding products falling in category 16)	only flavoured unripened cheese	-	100
03	Edible ices		-	150

[13] Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 354, 31.12.2008, p. 16.

[14] 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). OJ L 78, 17.03.2012, p. 12.

FCS[(a)] category number	FCS Food category	Restrictions / exception	MPL (mg/L or mg/kg as appropriate)	Previous MPL used in the EFSA ANS opinion (2009) (mg/L or mg/kg as appropriate)
04.2.1	Dried fruit and vegetables	only preserves of red fruit	-	200
04.2.2	Fruit and vegetables in vinegar, oil, or brine	only preserves of red fruit	-	200
04.2.3	Canned or bottled fruit and vegetables	only preserves of red fruit	-	200
04.2.4.1	Fruit and vegetable preparations excluding compote	only *mostarda di frutta*	20 [(b)]	200
04.2.4.1	Fruit and vegetable preparations excluding compote	only preserves of red fruit	-	200
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EEC	except *chestnut puree*	-	100
04.2.5.3	Other similar fruit or vegetable spreads	except *crème de pruneaux*	-	100
05.2	Other confectionery including breath refreshening microsweets	except candied fruit and vegetables	-	300
05.2	Other confectionery including breath refreshening microsweets	except candied fruit and vegetables and 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.	20 [(b)]	-
05.2	Other confectionery including breath refreshening microsweets	only candied fruit and vegetables	10 [(b)]	200
05.2	Other confectionery including breath refreshening microsweets	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 i.e. weddings, communion etc.	50 [(b)]	-
05.3	Chewing gum		10 [(b)]	300

FCS[(a)] category number	FCS Food category	Restrictions / exception	MPL (mg/L or mg/kg as appropriate)	Previous MPL used in the EFSA ANS opinion (2009) (mg/L or mg/kg as appropriate)
05.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	only decorations, coatings and sauces, except fillings	55 [(b)]	500
05.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	only fillings	55 [(b)]	300
06.6	Batters		55 [(b)]	500
07.2	Fine bakery wares		-	200
08.3.1	Non heat treated meat products	only *chorizo sausage/salchichon*	50	250
08.3.1	Non heat treated meat products	only *sobrasada*	-	200
08.3.3	Casings and coatings and decorations for meat	only edible casings	-	QS
08.3.3	Casings and coatings and decorations for meat	only decorations and coatings except edible external coating of *pasturmas*	55 [(b)]	500
09.2	Processed fish and fishery products including molluscs and crustaceans	only surimi and similar products and salmon substitutes	-	500
09.2	Processed fish and fishery products including molluscs and crustaceans	only fish paste and crustacean paste	-	100
09.2	Processed fish and fishery products including molluscs and crustaceans	only precooked crustacean	-	250
09.2	Processed fish and fishery products including molluscs and crustaceans	only smoked fish	-	100
09.2	Processed fish and fishery products including molluscs and crustaceans	only in salmon substitutes based on *Theragra chalcogramma* and *Pollachius virens*	200 [(c)]	-
09.3	Fish roe	except Sturgeons' eggs (Caviar)	200 [(b)]	300
12.2.2	Seasonings and condiments	only seasonings, for example curry powder, tandoori	-	500
12.4	Mustard		35 [(b)]	300
12.5	Soups and broths		-	50
12.6	Sauces	including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces	-	500
12.9	Protein products, excluding products covered in category 1.8	only meat and fish analogues based on vegetable proteins	10 [(b)]	100

FCS[(a)] category number	FCS Food category	Restrictions / exception	MPL (mg/L or mg/kg as appropriate)	Previous MPL used in the EFSA ANS opinion (2009) (mg/L or mg/kg as appropriate)
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)		10 [(b)]	50
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)		10 [(b)]	50
14.1.4	Flavoured drinks	excluding chocolate milk; malt products	10 [(b)]	100
14.2.3	Cider and perry	excluding *cidre bouché*	-	200
14.2.4	Fruit wine and made wine		1 [(b)]	200
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	except: spirit drinks as defined in Article 5(1) and sales denominations listed in Annex II, paragraphs 1-14 of Regulation (EC) No 110/2008 and spirits (preceded by the name of the fruit) obtained by maceration and distillation, Geist (with the name of the fruit or the raw material used), London Gin, Sambuca, Maraschino, Marrasquino or Maraskino and Mistrà	170 [(b)]	200
14.2.7.1	Aromatised wines	Except *americano, bitter vino*	50 [(b)]	200
14.2.7.1	Aromatised wines	Only *americano, bitter vino*	50 [(d) (d*)]	100
14.2.7.2	Aromatised wine-based drinks	Except *bitter soda, sangria, claria, zurra*	50 [(b)]	200
14.2.7.2	Aromatised wine-based drinks	Only *bitter soda*	50 [(d**)]	100
14.2.7.3	Aromatised wine-product cocktails		50 [(b)]	200
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol	Only alcoholic drinks with less than 15 % of alcohol	170 [(b)]	200
15.1	Potato-, cereal-, flour- or starch-based snacks	Excluding extruded or expanded savoury snack products	-	100
15.1	Potato-, cereal-, flour- or starch-based snacks	Only extruded or expanded savoury snack products	-	200
15.2	Processed nuts	Only savoury coated nuts	-	100

FCS[(a)] category number	FCS Food category	Restrictions / exception	MPL (mg/L or mg/kg as appropriate)	Previous MPL used in the EFSA ANS opinion (2009) (mg/L or mg/kg as appropriate)
16	Desserts excluding products covered in category 1, 3 and 4		10 [(b)]	150
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms		35 [(b)]	300
17.2	Food supplements supplied in a liquid form		10 [(b)]	100
17.3	Food supplements supplied in a syrup-type or chewable form		10 [(b)]	-
17.3	Food supplements supplied in a syrup-type or chewable form	Only solid food supplements	-	300
17.3	Food supplements supplied in a syrup-type or chewable form	Only liquid food supplements	-	100

(a): FCS: Food Categorisation System (food nomenclature) presented in the Annex II to Regulation (EC) No 1333/2008
(b): 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
(c): The total quantity of E 110, E 124 and the colours in Group III shall not exceed the maximum listed for Group III
(d): In americano E 100, E 101, E 102, E 104, E 120, E 122, E 123, E 124 are authorised individually or in combination
(d*): In bitter vino E 100, E 101, E 102, E 104, E 110, E 120, E 122, E 123, E 124, E 129 are authorised individually or in combination
(d**): In bitter soda E 100, E 101, E 102, E 104, E 110, E 120, E 122, E 123, E 124, E 129 are authorised individually or in combination
QS: quantum satis

2.1.2. Reported use levels or data on analytical levels of Ponceau 4R (E 124) in food

Most food additives in the EU are authorised at a specific MPL. However, a food additive may be used at a lower level than the MPL. Therefore, information on actual use levels is required to perform a more realistic exposure assessment, especially for those food additives for which no MPL is set and which are authorised for use at *quantum satis* (*QS)* levels. Ponceau R (E 124) is however not allowed at *QS* in any of the food categories (Table 2).

In the framework of Regulation (EC) No 1333/2008 on food additives and of Commission Regulation (EU) No 257/2010 regarding the re-evaluation of approved food additives, EFSA issued a public call[15] for usage and/or concentration data on Ponceau 4R (E 124) in March 2013 with a deadline of the end of November 2013.

Data on Ponceau 4R (E 124), including present use and use patterns (i.e. which food categories and subcategories contain the additive, proportion of foods within categories/subcategories in which it is used, and actual use levels (typical and maximum)), were requested from relevant stakeholders. European food manufacturers, national food authorities, research institutions, academics, food business operators and any other interested stakeholders were invited to submit usage and/or concentration data on Ponceau 4R (E 124) in foods. The data submission to EFSA followed the requirements of the EFSA Guidance on Standard Sample Description for Food and Feed (EFSA, 2010a).

In response to this public call, updated information on the actual use levels and analytical data related to Ponceau 4R (E 124) in foods was made available to EFSA by industry and Member States.

[15] Call for food additives usage level and/or concentration data in food and beverages intended for human consumption. Published: 27 March 2013. Deadline 15 September 2013. http://www.efsa.europa.eu/en/data/call/130327.htm

2.1.2.1. Summarised data on reported use levels of Ponceau 4R (E 124) in foods provided by industry

Industry provided EFSA with data (n = 17) on use levels of Ponceau 4R (E 124) in foods for five out of the 31 food categories in which Ponceau 4R is authorised. Reported use levels of Ponceau 4R (E 124) in foods were made available by the International Chewing Gum Association (ICGA), Association of the European Self-Medication Industry (AESGP) and FoodDrinkEurope (FDE).

Only usage data on three food categories in compliance with the current MPLs were taken into consideration for the exposure assessment. These usage data (n = 15) were provided by FDE for the following food categories: other confectionery including breath refreshening microsweets except candied fruit and vegetables and 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. (Food Categorisation System (FCS) 05.2); non heat treated processed meat only chorizo sausage/salchichon (FCS 08.3.1); flavoured drinks (FCS 14.1.4).

For the other two food categories in which the use of Ponceau 4R (E 124) is authorised, the reported use levels provided through the call for data did not comply with the current MPLs and have not been considered in the exposure assessment. Considering the call for data took place during amendment annex II to Regulation (EC) No 1333/2008 should enter into force, it was assumed that those usage data do not reflect the current use levels of Ponceau 4R (E 124) in the respective food categories.

Several values were reported by the industry (minimum, typical and maximum use levels) for the same product. For the purpose of the exposure assessment, maximum reported use levels as well as the mean of the typical reported use levels per food category were used in the refined exposure scenarios (Section 3.1).

The data provided by industry are summarised according to food category in Appendix A.

2.1.2.2. Summarised data on analytical results of Ponceau 4R (E 124) in foods from Member States

Analytical results from Member States were collected through the EFSA call for concentration data. Complete information on the methods used for analyses was not made available to EFSA. In total, 6 854 analytical results were reported by eight countries: Germany (n = 4 006), Austria (n=1003), Slovakia (n = 766), Hungary (n = 401), the Czech Republic (n = 328), Ireland (n = 203), Cyprus (n = 119) and Spain (n = 28). The data mainly related to flavoured drinks (FCS 14.1.4), fine bakery wares (FCS 07.2), confectionery (FCS 05.2) and edible ices (FCS 03). Foods were sampled between 2001 and 2013 and analysed during the same period of time. All the samples were analysed in accredited laboratories.

In order to include only recent data, analytical results sampled before 2004 (n = 39) were not considered in the exposure assessment. Moreover, 1022 analytical results expressed as qualitative values were not used, as they give only an indication of the presence or absence of the food additive in the food analysed (binary results). In total 333 out of the 1022 qualitative results indicated the presence of Ponceau 4R (E 124), most of them in edible ices and fine bakery wares.

Only 40 analytical results received from Member States related to food items sampled in 2013, and only six were sampled after 1 June 2013. In the absence of more recent data, data collected before 2013 were also considered for the refined exposure assessment scenario, provided that the values were below the currently authorised MPLs for Ponceau 4R (E 124).

Food samples were codified by the Member States in accordance with the Food Categorisation System defined in Regulation (EC) No 1333/2008, Annex II, Part D. A large number of samples (n=2976) could not be used in the current exposure assessment for the reasons explained hereafter. Most of them were on food items in which Ponceau 4R (E 124) was no longer authorised due to the amendment of Regulation (EC) No 1333/2008 by the Commission Regulation (EU) No 232/2012; these data refer mainly to Fine bakery wares (FCS 07.2), Edible ices (FCS 03), and Wine and other products defined

by Regulation (EC) No 1234/2007 (FCS 14.2.2). Other samples were not codified at a detailed enough level, thus not allowing their assignment to the correct authorised food category (e.g. FCS 14.2) or suggesting that they were derived from food categories for which Ponceau 4R (E 124) is not authorised; however, this could be caused by codification errors. Based on the information made available to EFSA on the food analysed (free text field), it was not always possible to distinguish whether there was a codification error or if Ponceau 4R (E 124) was indeed present in the food in which it is not authorised. In the majority of these samples, Ponceau 4R (E 124) was not detected (below the limit of detection (LOD)) or not quantified (below the limit of quantification (LOQ)), but in others (n = 641), analyses resulted in numerical values (i.e. with quantified levels of the food additive in food). These data mostly relate to processed fish and fishery products (FCS 9.2), processed food not covered by categories 1 to 17 (FCS 18), fine bakery wares (FCS 7.2), edible ices (FCS 03) and other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol (FCS 14.2.8). The high number of samples with numerical values in food categories where Ponceau 4R is not authorised can be explained by withdrawing a lot of MPLs in June 2013 and the use of data all collected before this date. The majority (≈ 62%) All of these food categories had MPLs before June 2013. The remaining samples with numerical values were on non-authorised food categories according to their codification.

Overall, 2817 out of the 6854 total analytical results reported for Ponceau 4R (E 124) corresponded to foods for which Ponceau 4R (E 124) is currently authorised. Out of this dataset, analytical results for Ponceau 4R (E 124) were not quantified (lower than the LOQ) in 380 samples and not detected (lower than the LOD) in 1826 samples; 611 samples provided numerical value (quantified).

Samples with numerical values (above the LOD/LOQ) were mainly derived from the following two food categories: other confectionery including breath freshening microsweets (FCS 05.2) and flavoured drinks (FCS 14.1.4). Out of these 611 samples, 301 contained levels of Ponceau 4R (E 124) above the new MPLs and were therefore discarded. Furthermore, in total 48 samples below LOQ or LOD were also discarded as their LOQ/LOD was above the corresponding current MPL. For the exposure assessment, EFSA considered only analytical data resulting from authorised uses of Ponceau 4R (E 124) at levels not exceeding the MPLs; exposure resulting from the presence of food additives in foods at levels above the MPLs forms part of risk management measures, e.g. non-compliance controls. For this reason, analytical results above the MPLs were not considered in the exposure assessment.

Finally, 2468 data were used in the current refined exposure assessment. These data covered 18 food categories out of the 31 for which Ponceau 4R (E 124) is authorised.

Appendix B shows the analytical results of Ponceau 4R (E 124) in foods as reported by Member States (the whole set of analytical data and data only from positive samples are reported) and considered in the exposure assessment.

2.1.3. Food consumption

2.1.3.1. EFSA Comprehensive European Food Consumption Database

Since 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been populated with national data on food consumption at a detailed level. Competent authorities in European countries provide EFSA with data on the level of food consumption by individual consumers from the most recent national dietary survey in their country (see the Guidance of EFSA 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a)).

The food consumption data gathered by EFSA were collected by different methodologies, and thus direct country-to-country comparison should be interpreted with caution. Depending on the food category and the level of detail used for exposure calculations, uncertainties could be introduced by

subjects' possible underreporting and/or misreporting of the consumption amounts. Nevertheless, the EFSA Comprehensive Database represents the best available source of food consumption data across Europe at present.

Consumption records were codified according to the FoodEx food classification system (EFSA, 2011b). Nomenclature from the FoodEx food classification system has been linked to the FCS, as presented in Annex II to Regulation (EC) No 1333/2008, for the exposure assessment.

2.1.3.2. Food items selected for the refined exposure assessment of Ponceau 4R (E 124)

The food categories for which the use of Ponceau 4R (E 124) is authorised were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx classification system food codes) at a detailed level (up to FoodEx level 4) (EFSA, 2011b).

Some food items are not referenced in the EFSA Comprehensive Database and could therefore not be taken into account for the present estimates. This resulted in an underestimation of the exposure. The food categories which were not taken into account are described below (in ascending order of FCS code):

- 04.2.4.1 Fruit and vegetable preparations excluding compote, only *mostarda di frutta*
- 05.4 Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4, only decorations, coatings and sauces, except fillings
- 05.4 Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4, only fillings
- 06.6 Batters
- 08.3.3 Casings and coatings and decorations for meat, only decorations and coatings except edible external coating of pasturmas
- 14.2.4 Fruit wine and made wine

The food category 'Other creams, only flavoured creams' (FCS 01.6.3) could not be differentiated from other kinds of creams included under the same food category (Cream and cream powder (FCS 01.6)). The same applied for differentiating flavoured cream from plain cream. Therefore, this food category was also not taken into account in the present estimates.

For some food categories, no data were provided to EFSA and could therefore not be taken into account in the refined scenarios (in ascending order of FCS code):

- 01.6.3 Other creams, only flavoured creams
- 04.2.4.1 Fruit and vegetable preparations excluding compote, only *mostarda di frutta*
- 05.4 Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4, only decorations, coatings and sauces, except fillings
- 05.4 Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4, only fillings
- 06.6 Batters

- 08.3.3 Casings and coatings and decorations for meat, only decorations and coatings except edible external coating of pasturmas
- 12.9 Protein products, only meat and fish analogues based on vegetable proteins
- 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).
- 14.2.7.1 Aromatised wines

It should be noted that, if Ponceau 4R (E 124) is nevertheless used in these food categories, the present refined exposure assessment might result in an underestimation of exposure to this food additive.

For some food categories, the restrictions which apply to the use of Ponceau 4R could not be taken into account in the exposure assessment, and therefore the whole food category was considered in the exposure assessment. This resulted in an overestimation of exposure from the following food categories:

- 09.3 Fish roe, except sturgeons' eggs (caviar): this exception could not be taken into account in the present exposure assessment, since no distinction is made in the FoodEx nomenclature between sturgeons' eggs and other fish eggs.
- 14.2.7.1 Aromatised wines and 14.2.7.2 Aromatised wine-based drinks: no distinction is possible between *Americano, bitter vino* and other products and *bitter soda* and other products in these food categories; therefore, the highest MPL and the highest use level reported within these categories were taken into account.
- 17.1/17.2/17.3, Food supplements: no distinction between the form of the food supplements (solid, liquid or syrup-type or chewable form) is possible within the FoodEx nomenclature; therefore, these three food categories were considered as a whole and the highest MPL and highest use level reported were taken into account.

Overall, 12 food categories were not taken into account in the exposure assessment either because they were not referenced in the EFSA Comprehensive Database or because no usage levels or analytical data were available to EFSA. Another three food categories were included in the exposure assessment without considering the restrictions defined in Annex II to Regulation (EC) No 1333/2008.

2.2. Methodologies

Dietary exposure to Ponceau 4R (E 124) from its use as a food colour was estimated using the approach adopted by the Panel at its 52nd plenary meeting.[16] This approach is to be followed to assess the exposure as part of the safety assessment of food additives under re-evaluation with the use of the food consumption data available within the EFSA Comprehensive Database, as presented in Table 3, and with the limitations described below.

EFSA estimated chronic exposure for the following population groups: toddlers, children, adolescents, adults and the elderly. For the present assessment, food consumption data were available from 26 different dietary surveys carried out in 17 different European countries, as shown in Table 3. Calculations were performed using individual body weights. Chronic exposure has been calculated based on individual consumptions over the total survey period excluding surveys with only one day per subject, which are considered as not adequate to assess repeated dietary exposure, as suggested by the EFSA Working Group on Food Consumption and Exposure (EFSA, 2011a). High percentile exposure was calculated for only those population groups in which the sample size was sufficiently

[16] http://www.efsa.europa.eu/en/events/event/140701a-m.pdf

large to allow calculation of the 95th percentile of exposure (EFSA, 2011a). Therefore, in the present assessment, high levels of exposure for toddlers from Belgium, Italy and Spain are not included.

Table 3: Population groups considered for the exposure estimates of Ponceau 4R (E 124)

Population	Age range	Countries with food consumption surveys covering more than one day
Toddlers	From 12 months up to and including 35 months of age	Belgium, Bulgaria, Finland, Germany, Italy, Netherlands, Spain
Children[(a)]	From 36 months up to and including 9 years of age	Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Spain, Sweden
Adolescents	From 10 years up to and including 17 years of age	Belgium, Cyprus, Czech Republic, Denmark, France, Germany, Italy, Latvia, Spain, Sweden
Adults	From 18 years up to and including 64 years of age	Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Spain, Sweden, UK
The elderly[(a)]	From 65 years of age	Belgium, Denmark, Finland, France, Germany, Hungary, Italy

(a): The terms 'children' and 'the elderly' correspond, respectively, to 'other children' and the combination of 'elderly' and 'very elderly' in the Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a).

Consumption records were codified according to the FoodEx classification system (EFSA, 2011b). Nomenclature from the FoodEx classification system has been linked to the FCS, as presented in Annex II to Regulation (EC) No 1333/2008, Part D, to perform exposure estimates. In practice, FoodEx food codes were matched to the FCS food categories and the exposure was calculated by multiplying MPLs (Table 2) and values reported in Appendix C for each food category by the corresponding consumption per kilogram body weight separately for each individual in the database. The exposure per food category was subsequently added to derive an individual total exposure per day. Finally, these exposure estimates were averaged over the number of surveys days per individual, resulting in an individual average exposure per day for the survey period. This was done for all individuals included in a survey and per age group, resulting in distributions of individual average exposure per survey and population group (Table 3). Based on these distributions, the mean and 95th percentile of exposures were calculated per survey for the total population and per population group.

Exposure assessment to Ponceau 4R (E 124) from its use as a food additive was carried out based on (1) MPLs set down in the EU legislation (defined as the *regulatory maximum level exposure assessment* scenario); and (2) use levels or analytical data (defined as the *refined exposure assessment* scenario) as provided by industry or Member States, respectively.

2.2.1. Regulatory maximum level exposure assessment scenario

The regulatory maximum level exposure assessment scenario is based on the MPLs as set in Annex II to Regulation (EC) No 1333/2008 and listed in Table 2.

The exposure estimates derived following this scenario should be considered the most conservative as they assume that the consumer will be continuously (over a lifetime) exposed to Ponceau 4R present in the food at the MPLs. However, it should be noted that as described in Section 2.1.3.2, some food items could not be taken into account in the present exposure assessment for all scenarios. This is nevertheless; expected to only represent a minor underestimation.

2.2.2. Refined exposure assessment scenario

The refined exposure assessment scenario is based on information on reported use levels provided by industry and analytical results submitted to EFSA by Member States. In the refined exposure scenario only food categories for which the above data are available can be considered.

Based on the available dataset, EFSA calculated two estimates based on different model populations:

(1) The brand-loyal consumer scenario: this scenario assumes that a consumer is exposed long term to the food additive present at the maximum reported use/analytical level for one food category. This exposure estimate is calculated as follows:

- combining food consumption with the maximum of the maximum reported use levels or the maximum of the analytical results for the main contributing food category at the individual level;
- using the mean of the typical reported use levels or the mean of analytical results for the remaining food categories.

(2) The non-brand-loyal consumer scenario: this scenario assumes that a consumer is exposed long term to the food additive present at the mean reported use/analytical levels in food. This exposure estimate is calculated using the mean of the typical reported use levels or the mean of analytical results for all food categories.

In the refined exposure assessment scenario, concentration levels considered are extracted from the whole dataset received (i.e. reported use levels and analytical results). Considering left-censored analytical data (i.e. analytical results below the LOD or LOQ), the substitution method as recommended in the 'Principles and Methods for the Risk Assessment of Chemicals in Food' (WHO, 2009) and in the EFSA scientific report 'Management of left-censored data in dietary exposure assessment of chemical substances' (EFSA, 2010b) is used. Analytical data below the LOD or LOQ are assigned half of the LOD or LOQ value, respectively (medium bound). For each food category, the mean or median, as appropriate, is used. For the reported use levels, the mean typical reported use level for each food category is used.

If both reported use levels and analytical results are available for the same food category, the most reliable value is used.

For Ponceau 4R (E 124), the refined exposure assessment scenario was applied as described above. Appendix C summarises the concentration levels used in the assessment. Food categories with no or inadequate reported use/analytical levels of Ponceau 4R (E 124) were not considered in the exposure assessment. EFSA noted that, if Ponceau 4R (E 124) is nevertheless used in these food categories, the refined exposure assessment might give an underestimation of the exposure to this food additive.

3. Assessment

3.1. Exposure to Ponceau 4R (E 124) from its use as a food additive

Table 4 summarises the anticipated exposure to Ponceau 4R (E 124) from its use as a food additive for all five population groups (Table 3). Detailed results per population group and survey are presented in Appendix D.

Table 4: Summary of anticipated exposure to Ponceau 4R (E 124) from its use as a food additive according to the regulatory maximum level exposure scenario and the refined exposure scenarios in five population groups (min–max across the dietary surveys in mg/kg bw per day)

	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (> 65 years)
Regulatory maximum level exposure assessment scenario					
• Mean	0.03-0.23	0.02-0.20	0.01-0.13	0.01-0.08	0.01-0.03
• High level (95th percentile	0.11-0.51	0.07-0.51	0.06-0.34	0.05-0.21	0.02-0.10
Refined estimated exposure assessment scenario					
Brand-loyal scenario					
• Mean	0.02-0.20	0.02-0.17	0.01-0.10	0.01-0.07	0.004-0.03
• High level (95th percentile	0.09-0.46	0.07-0.44	0.06-0.27	0.05-0.20	0.02-0.09
Non-brand-loyal scenario					
• Mean	0.01-0.16	0.01-0.14	0.01-0.09	0.01-0.05	0.003-0.01
• High level (95th percentile	0.03-0.38	0.06-0.35	0.05-0.22	0.03-0.15	0.01-0.05

3.2. Main food categories contributing to exposure to Ponceau 4R (E 124)

The main food categories contributing to total mean exposure to Ponceau 4R (E 124) (> 5 % of total exposure) according to the regulatory maximum level exposure scenario and the refined exposure assessment scenarios, as well as the number of surveys in which each food category is contributing, are shown in Tables 5, 6 and 7, respectively.

Table 5: Main food categories contributing to the total mean exposure to Ponceau 4R (E 124) using the regulatory maximum level exposure scenario (> 5 % of total exposure), and number of surveys to which each food category contributes

FCS category number	FCS food category	Toddlers	Children	Adolescents	Adults	The elderly
		Range of % contribution to the total exposure (number of surveys) [(a)]				
01.4	Flavoured fermented milk products including heat-treated products	9.4-75.2 (7)	8.1-29.4 (10)	6-11 (4)	5.4-15.2 (6)	6.8-13.1 (5)
05.2	Other confectionery including breath freshening microsweets	5.4-8.9 (2)	5.2-16.6 (7)	5.6-8.7 (4)	7.4-8.1 (2)	
09.2	Processed fish and fishery products including molluscs and crustaceans	8.8-68.4 (4)	9.9-81.3 (10)	9.4-49.2 (10)	9.7-43.8 (11)	10.5-58.5 (4)
09.3	Fish roe		10.2-10.2 (1)	5.5-5.5 (1)	7.1-7.1 (1)	6-6 (1)
12.4	Mustard				6-6 (1)	6.2-6.2 (1)
14.1.4	Flavoured drinks	16.7-81.5 (5)	13.6-93.7 (15)	37.1-89 (12)	29.6-83.6 (15)	10.4-77.3 (7)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts			7.1-11.5 (2)	6.6-46.2 (11)	8-62.2 (6)

FCS category number	FCS food category	Toddlers	Children	Adolescents	Adults	The elderly
		Range of % contribution to the total exposure (number of surveys) [a]				
16	Desserts excluding products covered in categories 1, 3 and 4	16.3-35.1 (2)	5.1-14.2 (7)	5.3-9.9 (3)	6.2-7.7 (2)	7.4-13.5 (3)
17	Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children					5.9-5.9 (1)

(a): The total number of surveys may be greater than the total number of countries listed in Table 3, as some countries submitted more than one survey for a specific age range.

Table 6: Main food categories contributing to the total mean exposure to Ponceau 4R (E 124) using the brand-loyal refined exposure scenario, (> 5 % of total exposure) and number of surveys to which each food category contributes

FCS category number	FCS food category	Toddlers	Children	Adolescents	Adults	The elderly
		Range of % contribution to the total exposure (Number of surveys)[a]				
01.4	Flavoured fermented milk products including heat-treated products	7.5-75 (7)	8.1-23.1 (7)	7.2-7.2 (1)	7.3-12.1 (3)	5.3-11.3 (4)
05.2	Other confectionery including breath freshening microsweets	6.9-6.9 (1)	7.7-13.3 (2)	5.2-5.2 (1)	6.9-6.9 (1)	
09.2	Processed fish and fishery products including molluscs and crustaceans	7.6-68.7 (4)	9.1-80.7 (10)	8.1-46.2 (10)	8.1-42.3 (11)	9.3-60 (4)
09.3	Fish roe		9.2-9.2 (1)		5.2-5.2 (1)	5.3-5.3 (1)
14.1.4	Flavoured drinks	20.9-85.6 (5)	15.7-95.9 (15)	41.8-91.8 (12)	34.6-90.5 (15)	12.8-83.8 (7)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts			6.7-11.7 (2)	6.1-44.6 (11)	8.2-66.2 (6)
16	Desserts excluding products covered in categories 1, 3 and 4	5.3-44.4 (3)	5.6-15 (8)	6.1-10.5 (3)	5.5-9.2 (3)	8.7-17 (3)

(a): The total number of surveys may be greater than the total number of countries listed in Table 3, as some countries submitted more than one survey for a specific age range.

Table 7: Main food categories contributing to the total mean exposure to Ponceau 4R (E 124) using the non-brand loyal refined exposure scenario, (> 5 % of total exposure) and number of surveys to which each food category contributes

FCS category number	FCS food category	Toddlers	Children	Adolescents	Adults	The elderly
		Range of % contribution to the total exposure (Number of surveys)[(a)]				
01.4	Flavoured fermented milk products including heat-treated products	5.5-58.1 (6)	5.7-15.6 (7)		5-13 (3)	5.1-16.5 (4)
05.2	Other confectionery including breath freshening microsweets		6.4-8.2 (2)		6.4-6.4 (1)	5.3-5.3 (1)
09.2	Processed fish and fishery products including molluscs and crustaceans	7.9-78.7 (4)	9.3-80.8 (10)	8.4-44.5 (10)	8.7-43 (11)	11.8-60.2 (4)
09.3	Fish roe		6.6-6.6 (1)		5.8-5.8 (1)	7.4-9.9 (2)
14.1.4	Flavoured drinks	6.2-92.9 (6)	16.8-97.8 (15)	41.7-93 (12)	41.4-97.7 (15)	13.3-97.5 (7)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts					7.6-11.1 (2)
16	Desserts excluding products covered in categories 1, 3 and 4	6.5-66 (3)	7.4-19 (8)	5.5-13 (4)	6.9-11.8 (3)	12.5-21.8 (3)

(a): The total number of surveys may be greater than the total number of countries listed in Table 3, as some countries submitted more than one survey for a specific age range.

3.3. Uncertainty analysis

According to the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2006), the following sources of uncertainties have been considered. These have been already presented in the sections above and are summarised below.

Table 8: Qualitative evaluation of the influence of uncertainties

Sources of uncertainties	Direction [(a)]
Consumption data: different methodologies/representativeness/underreporting/ misreporting/no portion size standard	+/–
Use of data from food consumption survey of only a few days to estimate long-term (chronic) exposure	+
Correspondence of reported use levels and analytical data to the food items in the EFSA Comprehensive Food Consumption Database: uncertainties to which precise types of food the use and analytical levels refer to	+/–
MPLs and concentration data (reported use or analytical levels) considered applicable for all items within the entire food category	+
Regulatory maximum level exposure scenario: use of MPLs in exposure assessment	+
Refined estimated exposure scenario: food categories not taken into account (because no use/analytical data were available for the food category or food category not available within FoodEx nomenclature)	–
Refined estimated exposure scenario: not addressing data in non-authorised food categories (n=2976) and data above MPLs (n=301)	–
Brand-loyal exposure model: exposure calculations based on the maximum reported use / maximum analytical level for one food category and mean reported uses / mean analytical levels for the other food categories	+/–
Non-brand loyal exposure model: exposure calculations based on the mean reported use / mean analytical levels	+/–

Sources of uncertainties	Direction [(a)]
Exposure through colour lakes not included in the assessment	–
Uncertainty in possible national differences in use levels of food categories, concentration data not fully representative of foods on the EU market	+/–

(a): + = uncertainty with potential to cause overestimation of exposure; - = uncertainty with potential to cause underestimation of exposure.

EFSA considered the impact of the uncertainties in the exposure assessment for Ponceau 4R (E 124) and concluded that overall, uncertainty could lead to an overestimation of the calculated exposure estimates.

3.4. Discussion

EFSA has performed an updated exposure assessment for Ponceau 4R (E 124) taking into consideration (1) the MPLs set down in the EU legislation (defined as the *regulatory maximum level exposure assessment* scenario); and (2) newly submitted data on its actual uses by industry and analytical data reported by Member States (defined as the *refined exposure assessment* scenario).

This second exposure assessment scenario was based on the dataset available and comprised of the calculation of two refined exposure estimates considering different assumptions: a 'brand-loyal consumer' scenario, in which it was assumed that a consumer is exposed long-term to the food additive present at the maximum reported use/analytical level for the main contributing food category per individual and at the mean reported use/analytical levels for the remaining food categories; and a 'non-brand-loyal consumer' scenario, in which it was assumed that a consumer is exposed long-term to the food additive present at the mean reported use/analytical levels in all food categories. Because of the above-mentioned assumptions, and the use of concentration data (reported use/analytical levels), the refined exposure scenario is considered a more realistic approach than the 'regulatory maximum level exposure assessment' scenario. Exposure estimates derived following this last scenario should be considered most conservative as this scenario assumes that the consumer will be continuously (over a lifetime) exposed to a food additive present in food at the MPLs.

The present exposure estimates were based on individual food consumption data available in the EFSA Comprehensive Database. It should be mentioned that some food categories (n = 6) were not referenced in the consumption database and were therefore not included in the present estimates. Those food categories were however minor in terms of consumption: *mostarda di frutta*, decorations, coatings and fillings, batters, casing and coating and decorations for meat, fruit wine and made wine (Appendix C). It is expected that not including these six food categories in the exposure assessment had a negligible effect on the exposure estimates reported here. The same applies to the four food categories with no analytical data or usage levels. On the other hand, for other food categories, the restrictions which apply to the use of Ponceau 4R could not be taken into account and the whole food category was considered for the exposure estimates, resulting in an overestimation.

Despite these limitations in the linking of the food categories for which usage/analytical data were provided and the FoodEx food groups coded in the Comprehensive Database, the food consumption data used in the present assessment were more detailed than the data used in the previous exposure assessment (EFSA ANS Panel, 2009). As a consequence, some food items, considered in 2009, could be removed from the present exposure estimates (e.g. chocolate milk and malt products from the flavoured drinks food category) as the use of Ponceau 4R (E 124) in these items is not authorised. Exclusion of non-relevant food subgroups resulted in a more precise estimation of the exposure.

According to the 'regulatory maximum level exposure assessment' scenario, mean exposure to Ponceau 4R (E 124) from its use as a food additive ranged from 0.01 mg/kg bw per day for the elderly to 0.23 mg/kg bw per day for toddlers. The high level exposure to Ponceau 4R (E 124) according to this scenario ranged from 0.02 to 0.51 mg/kg bw per day in the elderly and children, respectively. The main food categories contributing to the total mean exposure estimates for all populations in this scenario were flavoured drinks, processed fish and fishery products and for adults and the elderly,

alcoholic beverages. The exposure estimates were much lower (by a factor of around 5 to 50 depending on the population group and whether the estimates were for the mean or high level exposure) than those obtained from the evaluation carried out in 2009 (EFSA ANS Panel, 2009). However, the estimates cannot be accurately compared owing to the amendment of Annex II to Regulation (EC) No 1333/2008 in 2012. Following the conclusions of the EFSA opinion on Ponceau 4R (E 124) adopted in 2009 by the ANS Panel (EFSA ANS Panel, 2009), Annex II to Regulation (EC) No 1333/2008 was amended as regards the conditions of use and the use levels for Sunset Yellow FCF (E 110), Quinoline Yellow (E 104) and Ponceau 4R (E 124) (Commission Regulation (EU) No 232/2012[17]). For Ponceau 4R (E 124), many MPLs were withdrawn (n = 24) or decreased by a factor 1.2 to 200 (n = 29), depending on the food category, applicable from 1 June 2013. The differences in the outcomes of the current and previous exposure estimates for Ponceau 4R (E 124) using the MPL scenario are therefore very likely the result of the use of lower MPLs for some food categories and due to the absence of others food categories for which there is no MPL anymore. It is also a result of the availability of more detailed consumption data covering a range of European countries. Indeed, some of the children's consumption surveys currently included in the EFSA Comprehensive Database were also used in the opinion of the ANS Panel on Ponceau 4R (E 124) in 2009, but the food categories used in the previous assessment were broader than those available in FoodEx, used in the present assessment. Furthermore, in the current assessment, individual food consumption data were used to estimate dietary exposure, whereas, in the 2009 ANS opinion, only summary statistics were available. Moreover, for adults, only UK consumption data were available (Tennant, 2006).

Despite the fact that the exposure estimates derived from the MPL scenario in the current assessment do not exceed the ADI, it was decided that an exposure assessment using new data submitted to EFSA should also be performed. For the refined exposure assessment, the differences between the current and the previous assessment are the result of the newly available information on reported levels, an updated exposure scenario, new food consumption data and a refined selection of food items within the FoodEx nomenclature. EFSA noted that updated information on the actual use levels of Ponceau 4R (E 124) in foods and beverages made available by the industry covered only a few (n=3) of the food categories in which this food additive is authorised. The majority of analytical data on Ponceau 4R (E 124) in foods provided by Member States were collected before June 2013 and may therefore not be up to date as regards its conditions of use (Commission Regulation (EU) No 232/2012), as mentioned above. However, in the absence of more recent data, data collected before 2013 were also used for the refined exposure assessment scenario, provided that the values were below the currently authorised MPLs of use for Ponceau 4R (E 124), values above MPL were therefore excluded from the present exposure assessment (Section 2.1.2.2). This was also true for analysed values analysed from 2013 onwards. In addition, many data were available on food categories in which Ponceau 4R (E 124) is no longer authorised, in accordance with the 2012 amendment of Annex II to Regulation (EC) No 1333/2008. These data were also discarded. It was noted that for 10 food categories in which the use of Ponceau 4R (E 124) as a food additive is authorised, neither usage data nor quantified analytical data were reported.

According to the *refined brand-loyal assessment exposure* scenario, mean exposure to Ponceau 4R (E 124) from its use as a food additive ranged from 0.004 mg/kg bw per day for the elderly to 0.20 mg/kg bw per day for toddlers. The high level exposure to Ponceau 4R (E 124) ranged from 0.02 to 0.46 mg/kg bw per day, for the same population groups, respectively. The main food categories contributing to the total mean exposure estimates for all populations in this scenario were flavoured drinks and processed fish and fishery products and for adults and the elderly, alcoholic beverages.

According to the *refined non-brand-loyal assessment exposure* scenario, mean exposure to Ponceau 4R (E 124) from its use as a food additive ranged from 0.003 mg/kg bw per day for the elderly to 0.16 mg/kg bw per day for toddlers. The high exposure to Ponceau 4R (E 124) according to this scenario

[17] 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). OJ L 78, 17.03.2012, p. 12.

ranged from 0.01 to 0.38 mg/kg bw per day for the same population groups, respectively. The main contributing food categories for all populations were flavoured drinks and processed fish and fishery products.

The exposure estimates were considerably lower at the mean and high exposure levels, for both children and adults, in the current assessment compared to the 2009 assessment. However, a reliable comparison with the previous assessment is not possible because of the different approaches used. In the 2009 assessment, the exposure calculation was based on maximum usage levels available and MPLs (if no usage levels were available) for all food categories for which the use of Ponceau 4R (E 124) was authorised at that time, whereas in the current assessment, besides maximum analytical levels, mean analytical levels were also used and the food categories with no reported use level/analytical value were not included in the assessment (Appendix C). The latter was true for 10 food categories. Therefore, it should be noted that, if nevertheless, Ponceau 4R (E 124) is used in the food categories not considered in the current exposure estimate, the refined exposure assessment might result in underestimation of exposure to Ponceau 4R (E 124). However, as discussed earlier, the underestimation is likely to be negligible considering the food categories not taken into account. EFSA also noted that the refined exposure estimates will not cover future changes to the level of use of Ponceau 4R (E 124). As mentioned earlier, EFSA considered only analytical data resulting from authorised uses of Ponceau 4R (E 124) at levels not exceeding the MPLs. Exposure resulting from the presence of food additives in foods at levels above the MPLs is part of risk management measures, e.g. non-compliance controls. For this reason, analytical results above the MPLs were not considered in the current refined exposure estimate scenario.

The overall estimates of the present exposure assessment were lower than those obtained from the previous exposure assessment performed by the ANS Panel in 2009 (EFSA ANS Panel, 2009), and none exceeded the ADI of 0.7 mg/kg bw per day established for Ponceau 4R (E 124).

4. Conclusions

The current exposure estimates for Ponceau 4R (E 124) provide an update to the exposure assessment performed in 2009 (EFSA ANS Panel, 2009).

In comparison with the previous assessment, the current exposure estimates for Ponceau 4R (E 124) based on the MPL scenario were much lower (by a factor of around 5 to 50 depending on the population group and the mean or high level) owing to the amendment of Annex II to Regulation (EC) No 1333/2008 in 2012 (Commission Regulation (EU) No 232/2012). For Ponceau 4R (E 124), many MPLs were withdrawn (n = 24) or decreased by a factor 1.2 to 200 (n = 29), depending on the food category, applicable from 1 June 2013.

Concentration data received on Ponceau 4R (E 124), reported either by industry or Member States, covered 21 of the 31 authorised uses of Ponceau 4R (E 124) as a food additive. No additional information was provided to EFSA for some food categories, which were therefore not taken into account in the refined exposure assessment scenarios. Based on the refined scenarios, the current estimates were considerably lower at the mean and high exposure levels, for both children and adults than the 2009 assessment.

EFSA concluded that, using MPLs (regulatory maximum level exposure assessment scenario) and usage and/or analytical levels (refined exposure assessment scenario), exposure estimates did not exceed the ADI of 0.7 mg/kg bw per day in any population.

DOCUMENTATION PROVIDED TO EFSA

1. FoodDrinkEurope (FDE). Data on usage levels of Ponceau 4R (E 124). Submitted on 29 November 2013.

2. International Chewing Gum Association (ICGA). Data on usage levels of Ponceau 4R (E 124). Submitted on 29 November 2013.

3. Association of the European Self-Medication Industry (AESGP). Data on usage levels of Ponceau 4R (E 124). Submitted on 29 November 2013.

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APPENDICES

Appendix A. Summary of reported use levels of Ponceau 4R (E 124) provided by industry (mg/L or mg/kg as appropriate)

FCS Category number	FCS Food category	restrictions/exception	MPL	Number of data	Reported use levels from industry		Information provided by
					Typical mean (Range)	Highest maximum level	
05.2	Other confectionery including breath refreshening microsweets	except candied fruit and vegetables and 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.	20	1	15.0	20.0	FDE
08.3.1	Non heat treated meat products	only chorizo sausage/salchichon	50	1	50.0	50.0	FDE
14.1.4	Flavoured drinks	excluding chocolate milk; malt products	10	13	7.9 (4-10)	10.0	FDE

FDE, FoodDrinkEurope

Appendix B. Summary of analytical results of Ponceau 4R (E 124) provided by Member States (mg/L or mg/kg as appropriate)

FCS Category number	FCS Food category	MPL	n	%LC	Range LOD		Range LOQ		All data				Positive values				
					min	max	min	max	min	median	mean	max	n	min	median	mean	max
01.4	Flavoured fermented milk products including heat treated products	5	7	100.0	0.0	8.0	0.0	8.0	0.0	0.3	1.4	4.0					
05.2	Other confectionery including breath refreshening microsweets - except candied fruit and vegetables and 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.	20	704	75.7	0.0	20.0	0.1	60.0	0.1	2.5	5.2	20.0	171	0.1	8.0	8.5	20.0
05.2	Other confectionery including breath refreshening microsweets - only candied fruit and vegetables	10	54	96.3	0.0	20.0	0.1	60.0	0.1	0.3	1.9	10.0	2	5.0	6.4	6.4	7.9
05.2	Other confectionery including breath refreshening microsweets - 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 i.e. weddings, communion etc.	50	77	63.6	0.0	20.0	0.1	60.0	0.0	2.9	9.0	48.4	28	0.6	18.2	19.6	48.4
05.3	Chewing gum	10	22	59.1	0.0	20.0	0.1	60.0	0.5	5.0	5.2	10.0	9	2.0	5.0	5.3	10.0
05.4	Decorations, coatings and fillings, except fruit based fillings covered by category	55	6	66.7	0.2	0.8	0.7	2.4	0.1	0.7	17.0	51.5	2	49.1	50.3	50.3	51.5

FCS Category number	FCS Food category	MPL	n	%LC	Range LOD		Range LOQ		All data				Positive values				
					min	max	min	max	min	median	mean	max	n	min	median	mean	max
	4.2.4																
08.3.1	Non heat treated meat products	50	2	50.0	0.0	0.1	0.1	0.1	0.0	16.5	16.5	33.0	1	33.0	33.0	33.0	33.0
09.2	Processed fish and fishery products including molluscs and crustaceans	200	9	0.0	0.0	0.2	0.1	0.5	7.0	127.1	103.5	163.0	9	7.0	127.1	103.5	163.0
09.3	Fish roe	200	10	30.0	0.0	0.2	0.1	2.0	0.0	86.0	63.6	186.0	7	18.2	86.0	90.6	186.0
12.4	Mustard	35	6	100.0	0.2	0.2	0.5	5.0	0.3	2.5	1.8	2.5					
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	10	37	100.0	0.0	20.0	0.0	60.0	0.0	10.0	7.2	10.0					
14.1.4	Flavoured drinks - excluding chocolate milk; malt products	10	1180	95.0	0.0	20.0	0.0	60.0	0.0	0.5	2.5	10.0	59	0.7	4.0	4.4	10.0
14.2.4	Fruit wine and made wine	1	35	100.0	0.0	0.9	0.1	4.3	0.1	0.5	0.4	0.5					
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	170	132	90.2	0.0	20.0	0.0	60.0	0.0	0.1	5.5	156.4	13	0.6	5.2	40.6	156.4
14.2.7.2	Aromatised wine-based drinks - except *bitter soda, sangria, claria, zurra*	50	4	100.0	0.0	0.5	0.0	1.0	0.0	0.0	0.1	0.3					
14.2.7.2	Aromatised wine-based drinks - only *bitter soda*	50	1	100.0	20.0	20.0	60.0	60.0	10.0	10.0	10.0	10.0					
14.2.7.3	Aromatised wine-product cocktails	50	40	97.5	0.0	20.0	0.0	60.0	0.0	0.1	2.2	10.0	1	9.3	9.3	9.3	9.3
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol	170	89	96.6	0.0	20.0	0.0	60.0	0.0	0.5	3.3	34.0	3	12.7	21.0	22.6	34.0
16	Desserts excluding products covered in category 1, 3 and 4	10	46	91.3	0.0	20.0	0.0	60.0	0.0	10.0	6.6	10.0	4	7.1	8.0	7.8	8.2

FCS Category number	FCS Food category	MPL	n	%LC	Range LOD		Range LOQ		All data				Positive values				
					min	max	min	max	min	median	mean	max	n	min	median	mean	max
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms	35	5	80.0	2.0	3.0	6.0	9.0	1.0	1.0	5.2	21.4	1	21.4	21.4	21.4	21.4
17.2	Food supplements supplied in a liquid form	10	2	100.0	0.2	0.8	0.5	2.4	0.3	0.3	0.3	0.4					

%LC: Percentage of left-censored data

Appendix C. Concentration levels of Ponceau 4R (E 124) used in the refined exposure scenarios (mg/L or mg/kg as appropriate)

FCS Category number	FCS Food category	Restrictions/exceptions	MPL	Concentration levels used in the refined exposure assessment		Comments
				Mean	Max	
01.4	**Flavoured fermented milk products including heat treated products**		5	1.4	4	Analytical data
01.6.3	**Other creams**	only flavoured creams	5			Not taken into account (overestimation by using FoodEx codes/no data available)
04.2.4.1	**Fruit and vegetable preparations excluding compote**	only mostarda di frutta	20			Not taken into account (no corresponding FoodEx code)
05.2	**Other confectionery including breath refreshening microsweets**	except candied fruit and vegetables and 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.	20	5.2	20	Analytical data
05.2	**Other confectionery including breath refreshening microsweets**	only candied fruit and vegetables	10	1.9	10	Analytical data
05.2	**Other confectionery including breath refreshening microsweets**	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 i.e. weddings, communion etc.	50	9	48	Analytical data
05.3	**Chewing gum**		10	5.2	10	Analytical data
05.4	**Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4**	only decorations, coatings and sauces, except fillings	55			Not taken into account (no corresponding FoodEx code)
05.4	**Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4**	only fillings	55			Not taken into account (no corresponding FoodEx code)

FCS Category number	FCS Food category	Restrictions/exceptions	MPL	Concentration levels used in the refined exposure assessment		Comments
				Mean	Max	
06.6	**Batters**		55			Not taken into account (no corresponding FoodEx code)
08.3.1	**Non heat treated meat products**	only *chorizo sausage/salchichon*	50	50	50	Reported use levels
08.3.3	**Casings and coatings and decorations for meat**	only decorations and coatings except edible external coating of *pasturmas*	55			Not taken into account (no corresponding FoodEx code)
09.2	**Processed fish and fishery products including molluscs and crustaceans**	only in salmon substitutes based on *Theragra chalcogramma* and *Pollachius virens*	200	127	163	Analytical data
09.3	**Fish roe**	except Sturgeons' eggs (Caviar)	200	86	186	Analytical data
12.4	**Mustard**		35	2.5	2.5	Analytical data
12.9	**Protein products, excluding products covered in category 1.8**	only meat and fish analogues based on vegetable proteins	10			Not taken into account (no analytical data or reported use levels)
13.2	**Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)**		10	10	10	Analytical data
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)**		10			Not taken into account (no analytical data or reported use levels)
14.1.4	**Flavoured drinks**	excluding chocolate milk; malt products	10	7.9	10	Reported use levels
14.2.4	**Fruit wine and made wine**		1			Not taken into account (no corresponding FoodEx code)

FCS Category number	FCS Food category	Restrictions/exceptions	MPL	Concentration levels used in the refined exposure assessment		Comments
				Mean	Max	
14.2.6	**Spirit drinks as defined in Regulation (EC) No 110/2008**	except: spirit drinks as defined in article 5(1) and sales denominations listed in Annex II, paragraphs 1-14 of Regulation 110/2008 and spirits (preceded by the name of the fruit) obtained by maceration and distillation, London Gin, Sambuca, Maraschino, Marrasquino or Maraskino and Mistrà.	170	5.5	156.4	Analytical data
14.2.7.1	**Aromatised wines**	Except *americano, bitter vino*	50	2.2	10	Analytical data
14.2.7.1	**Aromatised wines**	only *americano, bitter vino*	50			
14.2.7.2	**Aromatised wine-based drinks**	except *bitter soda, sangria, claria, zurra*	50			
14.2.7.2	**Aromatised wine-based drinks**	only *bitter soda*	50			
14.2.7.3	**Aromatised wine-product cocktails**		50			
14.2.8	**Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol**	only alcoholic drinks with less than 15 % of alcohol	170	3.3	34	Analytical data
16	**Desserts excluding products covered in category 1, 3 and 4**		10	10	10	Analytical data
17.1	**Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms**		35	3.8	24.4	Analytical data
17.2	**Food supplements supplied in a liquid form**		10			
17.3	**Food supplements supplied in a syrup-type or chewable form**		10			

Appendix D. Summary of total estimated exposure to Ponceau 4R (E 124) from its use as a food additive for the regulatory maximum level exposure scenario (MPL scenario) and the refined exposure assessment scenarios per population group and survey: mean and high level (mg/kg bw per day)

	Number of subjects	MPLs scenario		Brand-loyal scenario		Non-brand-loyal scenario	
		Mean	High level	Mean	High level	Mean	High level
Toddlers							
Belgium (Regional Flanders)	36	0.23		0.20		0.16	
Bulgaria (NUTRICHILD)	428	0.03	0.13	0.02	0.12	0.02	0.10
Germany (DONALD 2006 2008)	261	0.06	0.33	0.05	0.27	0.04	0.22
Spain (enKid)	17	0.04		0.03		0.02	
Finland (DIPP 2003 2006)	497	0.03	0.11	0.02	0.09	0.01	0.03
Italy (INRAN SCAI 2005 06)	36	0.05		0.04		0.03	
Netherlands (VCP kids)	322	0.17	0.51	0.14	0.46	0.11	0.38
Children							
Belgium (Regional Flanders)	625	0.20	0.51	0.17	0.44	0.14	0.35
Bulgaria (NUTRICHILD)	433	0.05	0.20	0.05	0.18	0.04	0.15
Czech Republic (SISP04)	389	0.08	0.31	0.07	0.28	0.06	0.23
Germany (DONALD 2006 2008)	660	0.12	0.40	0.10	0.34	0.08	0.28
Denmark (Danish Dietary Survey)	490	0.10	0.23	0.09	0.20	0.07	0.16
Spain (enKid)	156	0.06	0.22	0.05	0.22	0.04	0.17
Spain (NUT INK05)	399	0.06	0.26	0.05	0.21	0.04	0.17
Finland (DIPP 2003 2006)	933	0.05	0.15	0.04	0.12	0.03	0.09
Finland (STRIP)	250	0.08	0.19	0.07	0.18	0.05	0.14
France (INCA2)	482	0.12	0.34	0.10	0.28	0.08	0.23
Greece (Regional Crete)	839	0.02	0.07	0.02	0.07	0.01	0.06
Italy (INRAN SCAI 2005 06)	193	0.08	0.48	0.06	0.39	0.05	0.30
Latvia (EFSA TEST)	189	0.04	0.17	0.04	0.15	0.03	0.13
Netherlands (VCP kids)	957	0.16	0.46	0.13	0.38	0.10	0.31
Sweden (NFA)	1473	0.20	0.49	0.16	0.38	0.13	0.32
Adolescents							
Belgium (Diet National 2004)	584	0.09	0.26	0.08	0.23	0.06	0.18
Cyprus (Childhealth)	303	0.01	0.06	0.01	0.06	0.01	0.05
Czech Republic (SISP04)	298	0.07	0.26	0.07	0.23	0.05	0.18
Germany (National Nutrition Survey II)	1011	0.05	0.20	0.04	0.18	0.03	0.14
Denmark (Danish Dietary Survey)	479	0.09	0.20	0.07	0.18	0.06	0.14
Spain (AESAN FIAB)	86	0.02	0.09	0.02	0.09	0.01	0.06
Spain (enKid)	209	0.04	0.14	0.04	0.14	0.03	0.11
Spain (NUT INK05)	651	0.04	0.15	0.04	0.13	0.03	0.10
France (INCA2)	973	0.05	0.16	0.05	0.13	0.04	0.11
Italy (INRAN SCAI 2005 06)	247	0.03	0.15	0.03	0.12	0.02	0.10
Latvia (EFSA TEST)	470	0.03	0.11	0.03	0.11	0.02	0.08

	Number of subjects	MPLs scenario		Brand-loyal scenario		Non-brand-loyal scenario	
		Mean	High level	Mean	High level	Mean	High level
Sweden (NFA)	1018	0.13	0.34	0.10	0.27	0.09	0.22
Adults							
Belgium (Diet National 2004)	1304	0.06	0.21	0.05	0.20	0.04	0.15
Czech Republic (SISP04)	1666	0.02	0.12	0.02	0.11	0.01	0.07
Germany (National Nutrition Survey II)	10419	0.03	0.14	0.03	0.13	0.02	0.10
Denmark (Danish Dietary Survey)	2822	0.04	0.13	0.03	0.11	0.02	0.08
Spain (AESAN)	410	0.03	0.12	0.03	0.11	0.02	0.09
Spain (AESAN FIAB)	981	0.02	0.08	0.02	0.07	0.01	0.05
Finland (FINDIET 2007)	1575	0.03	0.09	0.02	0.08	0.01	0.04
France (INCA2)	2276	0.03	0.10	0.02	0.09	0.02	0.07
United Kingdom (NDNS)	1724	0.04	0.13	0.03	0.11	0.02	0.07
Hungary (National Repr Surv)	1074	0.02	0.08	0.02	0.08	0.02	0.06
Ireland (NSIFCS)	958	0.04	0.14	0.03	0.12	0.02	0.06
Italy (INRAN SCAI 2005 06)	2313	0.01	0.05	0.01	0.05	0.01	0.03
Latvia (EFSA TEST)	1306	0.02	0.10	0.02	0.09	0.01	0.05
Netherlands (DNFCS 2003)	750	0.08	0.21	0.07	0.19	0.05	0.15
Sweden (Riksmaten 1997 98)	1210	0.06	0.17	0.05	0.13	0.03	0.09
The elderly							
Belgium (Diet National 2004)	1230	0.02	0.08	0.02	0.07	0.01	0.05
Germany (National Nutrition Survey II)	2496	0.01	0.06	0.01	0.05	0.01	0.04
Denmark (Danish Dietary Survey)	329	0.03	0.10	0.03	0.09	0.01	0.04
Finland (FINDIET 2007)	463	0.01	0.04	0.01	0.04	0.00	0.01
France (INCA2)	348	0.01	0.07	0.01	0.06	0.01	0.04
Hungary (National Repr Surv)	286	0.01	0.05	0.01	0.05	0.01	0.03
Italy (INRAN SCAI 2005 06)	518	0.01	0.02	0.00	0.02	0.00	0.01

ABBREVIATIONS

ADI	Acceptable Daily Intake
ANS Panel	Scientific Panel on Food Additives and Nutrient Sources added to Food
bw	body weight
EC	European Commission
EU	European Union
EXPOCHI	Individual food consumption data and exposure assessment studies for children
FAO	Food and Agricultural Organization
FCS	Food Categorisation System (food nomenclature) presented in Annex II of Regulation (EC) No 1333/2008
FDE	FoodDrinkEurope
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOD	limit of detection
LOQ	limit of quantification
MPL	Maximum Permitted Level
QS	*quantum satis*
SCF	Scientific Committee for Food
WHO	World Health Organization