

STATEMENT OF EFSA

Refined exposure assessment for Allura Red AC (E 129)¹

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ABSTRACT

Following a self-tasking request, the European Food Safety Authority (EFSA) carried out a refined exposure assessment for Allura Red AC (E 129) 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 Allura Red AC (E 129) used as a food additive. In that opinion, the Panel concluded that, at the high level, under both scenarios, that is using either the maximum permitted levels (MPLs) or the reported use levels provided by industry, intake estimates for 1- to 10-year old children can be above the Acceptable Daily Intake (ADI) of 7 mg/kg body weight (bw) per day. Following this conclusion, 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 and the EFSA for six out of the 51 food categories in which Allura Red AC (E 129) is authorised as a food additive; while analytical data from Member States were provided to EFSA for 35 food categories. Using MPLs and these new data, none of the exposure estimates exceeded the ADI of 7 mg/kg bw per day in any population.

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KEY WORDS

Allura Red AC, E 129, dietary exposure, EFSA Comprehensive European Food Consumption Database, food colours

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SUMMARY

Following the adoption by the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) in 2009 of a scientific opinion on the re-evaluation of Allura Red AC (E 129) used as a food additive, in which the Panel concluded that, at the high level, under both scenarios, that is using either the maximum permitted levels (MPLs) or the reported use levels provided by industry, intake estimates for 1- to 10-year old children can be above the Acceptable Daily Intake (ADI) of 7 mg/kg body weight (bw) per day, EFSA carried out a refined exposure assessment for this colour, taking into account additional information on its use and usage levels in foods.

Allura Red AC (E 129) is an azo dye authorised 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 1980 and 1981 and the Scientific Committee for Food (SCF) in 1984 and 1989.

In 2009, the ANS Panel re-evaluated Allura Red AC (E 129) as a food additive. The safety in use of Allura Red AC (E 129) was assessed on the basis of uses and use levels authorised in the legislation⁴ and of reported use levels, as provided by industry. The ANS Panel concluded that there was no reason to revise the ADI of 7 mg/kg body weight (bw) per day.

The ANS Panel concluded that both at the maximum permitted levels (MPLs) and maximum reported levels of use of Allura Red AC (E 129), intake estimates for 1- to 10-year old children at the high percentile (95th or 97.5th) can be above the ADI of 7 mg/kg bw per day.

The present review provides a refined exposure assessment for Allura Red AC (E 129) based on individual food consumption data which became available within the EFSA Comprehensive European Food Consumption Database and newly submitted information on the actual usage levels and analytical data of Allura Red AC (E 129) in foods as consumed, provided to EFSA by the food industry and Member States, following an EFSA call for data⁵ launched in March 2013.

Usage levels of Allura Red AC (E 129) reported by industry covered six out of the 51 authorised uses of Allura Red AC as a food additive, while analytical data from Member States covered 35 food categories.

In comparison with the previous assessment, the current exposure estimates based on the MPLs scenario were in the same order of magnitude at the mean level for all populations, while high exposure levels (95th percentile) were lower for all populations except adults. Based on the refined scenarios, the current estimates were lower for all populations at both the mean and high exposure level.

EFSA concluded that, using MPLs (*regulatory maximum level exposure assessment* scenario), exposure estimates were lower than those from the previous opinion of the ANS Panel in 2009 and did not exceed the ADI of 7 mg/kg bw per day in any population. This was also true for the refined exposure scenarios based on usage/analytical levels at both the mean and high (95th percentile) level.

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 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



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Abbreviations



1. 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,⁶ sunset yellow,⁷ ponceau $4R^8$). The Member States and stakeholders had informed the European Commission 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 make 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 1129/2011⁹) 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), Allura Red AC (E 129), 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), Allura Red AC (E 129), brilliant black BN (E 151)

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

⁶ EFSA, 2009. Scientific Opinion on the re-evaluation of Quinoline Yellow (E 104) as a food additive, ON-1329.

⁷ EFSA, 2009. Scientific Opinion on the re-evaluation of Sunset Yellow FCF (E 110) as a food additive, ON-1330.

⁸ EFSA, 2009. Scientific Opinion on the re-evaluation of Ponceau 4R (E 124) as a food additive, ON-1328.

⁹ 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 Allura Red AC (E 129) from its use as a food colour using the approach adopted by the Panel at its 52nd plenary meeting¹⁰ 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 concentration data from Member States (analytical data).

1.3. Additional information

Allura Red AC (E 129) 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 1980 and 1981 (JECFA, 1980, 1981) and the Scientific Committee for Food (SCF) in 1984 and 1989 (SCF, 1984, 1989).

In 2009, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) re-evaluated Allura Red AC (E 129) as a food additive (EFSA ANS Panel, 2009). The safety of the use of Allura Red AC (E 129) was assessed on the basis of uses and use levels authorised in the legislation¹¹ and of reported use levels, as provided by industry. The ANS Panel concluded that the database did not provide reason to revise the Acceptable Daily Intake (ADI) of 7 mg/kg body weight (bw) per day.

The ANS Panel concluded that, at the maximum reported levels of use of Allura Red AC (E 129), intake estimates were generally below the ADI, although, for 1- to 10-year old children, the high percentiles of exposure (95th) could be higher than the ADI of 7 mg/kg bw per day at the upper end of the range. The main contributors (> 10 %) to the total anticipated mean exposure of the adult population to Allura Red AC (E 129) were non-alcoholic beverages (53 %). For children, the main contributing food categories were non-alcoholic beverages (10 to 63 %), fine bakery wares (e.g. Viennoiserie, biscuits, cakes, wafers) (12 to 39 %) and desserts, including flavoured milk products (14 to 58 %). Sauces, seasonings (e.g. curry powder, tandoori), pickles, relishes, chutney and piccalilli accounted for 10 to 57 % in five countries.

Table 1 presents the dietary exposure to Allura Red AC (E 129) 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 Allura Red AC in children and the adult population
as calculated	in the previous ANS Panel opinion (EFSA ANS Panel, 2009) (mg/kg bw per day)

	UK, adults ^(a)	UK ^(a) and EXPOCHI ^(b) , children
	(>18 years old)	$(1-10 \text{ years old}, 15-30 \text{ kg body weight}^{(c)})$
Estimated exposure using MPLs		
Mean exposure	0.9	0.8–3.4
• Exposure 95th ^(b) or 97.5th percentile ^(a)	2.1	1.8–9.4
Estimated exposure using reported use levels		
Mean exposure	0.8	0.5–3.0
• Exposure 95th ^(b) or 97.5th percentile ^(a)	1.9	1.2-8.5

(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): Except for the Cypriot children, where the reported body weight was 54 kg for 11- to 14-year-old children.

¹⁰ http://www.efsa.europa.eu/en/events/event/140701a-m.pdf

¹¹ 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 Allura Red intake for children and toddlers according to two scenarios. Results show the diet exposure to the food additive in the range of 0.3 mg/kg bw per day (mean) to 4.0 mg/kg bw per day (high level consumers) for children (6-11 years old), and in the range of 0.5 mg/kg bw per day (mean) to 3.8 mg/kg bw per day (high level consumers) for toddlers (0.5 to <5 years old).

2. Data and methodologies

2.1. Data

2.1.1. Case of need and proposed uses of Allura Red AC (E 129)

MPLs of Allura Red AC (E 129) are defined in Annex II to Regulation (EC) No 1333/2008¹² on food additives, as amended.

Currently, Allura Red AC (E 129) is an authorised food colour in the EU, with MPLs ranging from 25 to 500 mg/kg in foods and at *quantum satis* (QS) in three food categories. In addition, Allura Red AC (E 129) is included in Group III of food colours with combined maximum limit and may therefore also be used in the food categories in which Group III food additives are allowed.

Table 2 summarises foods that are permitted to contain Allura Red AC (E 129) and the corresponding MPLs as set by Annex II to Regulation (EC) No 1333/2008.

Table 2:	Maximum permitted levels of Allura Red AC (E 129) in foods according to	Annex II of
Regulation (EC) No 1333/2008	

FCS ^(a) category number	Food category	E Number / Group	Maximum permitted level (mg/L or mg/kg as appropriate)	Restrictions
01.4	Flavoured fermented milk products including heat treated products	Group III	150	
01.6.3	Other creams	Group III	150	Only flavoured creams
01.7.1	Unripened cheese excluding products falling in category 16	Group III	150	Only flavoured unripened cheese
01.7.3	Edible cheese rind	Group III	quantum satis	
01.7.6	Cheese products (excluding products falling in category 16)	Group III	100	Only flavoured unripened products
03	Edible ices	Group III	150	
04.2.1	Dried fruit and vegetables	E 129	200 ^(b)	Only preserves of red fruit
04.2.2	Fruit and vegetables in vinegar, oil or brine	E 129	200 ^(b)	Only preserves of red fruit
04.2.3	Canned or bottled fruit and vegetables	E 129	200 ^(b)	Only preserves of red fruit
04.2.4.1	Fruit and vegetable preparations excluding compote	Group III	200	Only mostarda di frutta
04.2.4.1	Fruit and vegetable preparations excluding compote	E 129	200 ^(b)	Only preserves of red fruit

¹² Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 354, 31.12.2008, p. 16.



FCS ^(a)	Food category	E Number	Maximum	Restrictions
category number		/ Group	permitted level (mg/L or mg/kg as appropriate)	
05.2	Other confectionery including breath refreshening microsweets	Group III	300	Except candied fruit and vegetables
05.2	Other confectionery including breath refreshening microsweets	Group III	200	Only candied fruit and vegetables
05.3	Chewing gum	Group III	300	
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	Group III	500	Only decorations, coatings and sauces, except fillings
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	Group III	300	Only fillings
06.6	Batters	Group III	500	Only batters for coating
07.2	Fine bakery wares	Group III	200	
08.1	Fresh meat, excluding meat preparations as defined by Regulation (EC) No 853/2004	E 129	quantum satis	Only for the purpose of health marking
08.2	Meat preparations as defined by Regulation (EC) No 853/2004	E 129	25	Only <i>breakfast sausages</i> with a minimum cereal content of 6 % and <i>burger meat</i> with a minimum vegetable and/or cereal content of 4 % mixed within the meat. In these products, the meat is minced in such a way that the muscle and fat tissue are completely dispersed, so that fibre makes an emulsion with the fat, giving those products their typical appearance
08.3.2	Heat-treated meat products	E 129	25	Only <i>luncheon meat</i>
08.3.3	Casings and coatings and decorations for meat	Group III	500	Only decorations and coatings except edible external coating of <i>pasturmas</i>
08.3.3	Casings and coatings and decorations for meat	Group III	quantum satis	Only edible casings
09.2	Processed fish and fishery products including molluscs and crustaceans	Group III	500	Only surimi and similar products and salmon substitutes
09.2	Processed fish and fishery products including molluscs and crustaceans	E 129	250 ^(c)	Only precooked crustacean
09.3	Fish roe	Group III	300	Except sturgeons' eggs (caviar)
12.2.2	Seasonings and condiments	Group III	500	Only seasonings, for example curry powder, tandoori
12.4	Mustard	Group III	300	
12.5	Soups and broths	Group III	50	



FCS ^(a) category number	Food category	E Number / Group	Maximum permitted level (mg/L or mg/kg as appropriate)	Restrictions
12.6	Sauces	Group III	500	Including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces
12.9	Protein products, excluding products covered in category 1.8	Group III	100	Only meat and fish analogues based on vegetable proteins
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	Group III	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)	Group III	50	
14.1.4	Flavoured drinks	Group III	100	Excluding chocolate milk; malt products
14.2.3	Cider and perry	Group III	200	Excluding cidre bouché
14.2.4	Fruit wine and made wine	Group III	200	Excluding wino owocowe mark
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	Group III	200	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
14.2.7.1	Aromatised wines	Group III	200	Except americano, bitter vino
14.2.7.1	Aromatised wines	E 129	100 ^(d)	Only bitter vino
14.2.7.2	Aromatised wine-based drinks	Group III	200	Except bitter soda, sangria, claria, zurra
14.2.7.2	Aromatised wine-based drinks	E 129	100 ^(e)	Only bitter soda
14.2.7.3	Aromatised wine-product cocktails	Group III	200	



FCS ^(a)	Food category	E Number	Maximum	Restrictions
category	i oou category	/	permitted level	Restrictions
number		Group	(mg/L or	
		_	mg/kg as	
			appropriate)	
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol	Group III	200	Only alcoholic drinks with less than 15 % of alcohol and nalewka na winie owocowym, aromatyzowana nalewka na winie owocowym, nalewka na winie z soku winogronowego, aromatyzowana nalewka na winie z soku winogronowego, napój winny owocowy lub miodowy, aromatyzowany napój winny owocowy lub miodowy, wino owocowe niskoalkoholowe and aromatyzowane wino owocowe niskoalkoholowe
15.1	Potato-, cereal-, flour- or starch- based snacks	Group III	100	Excluding extruded or expanded savoury snack products
15.1	Potato-, cereal-, flour- or starch- based snacks	Group III	200	Only extruded or expanded savoury snack products
15.2	Processed nuts	Group III	100	Only savoury-coated nuts
16	Desserts excluding products covered in categories 1, 3 and 4	Group III	150	
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms	Group III	300	
17.2	Food supplements supplied in a liquid form	Group III	100	
17.3	Food supplements supplied in a syrup-type or chewable form	Group III	300	Only solid food supplements
17.3	Food supplements supplied in a syrup-type or chewable form	Group III	100	Only liquid food supplements

(a): FCS: Food categorisation System (food nomenclature) presented in the Annex II to Regulation (EC) No 1333/2008

(b): Maximum individually or for the combination of E 120, E 122, E 129, E 131, E 133.

(c): Maximum individually or for the combination of E 100, E 102, E 120, E 122, E 129, E 142, E 151, E 160e, E 161b.

(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.

(e): 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.

2.1.2. Reported use levels or data on analytical levels of Allura Red AC (E 129) 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 QS levels.

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 call¹³ for usage and/or concentration data on Allura Red AC (E 129) in March 2013 with deadline of mid-September 2013.

Data on Allura Red AC (E 129), 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, actual use levels (typical and maximum use levels), especially for the uses at QS), 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 Allura Red AC (E 129) 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 of Allura Red AC (E 129) in foods was made available to EFSA by industry and Member States.

2.1.2.1. Summarised data on reported use levels of Allura Red AC in foods provided by industry

Industry provided EFSA with data on use levels (n = 29) of Allura Red AC (E 129) in foods for six out of the 51 food categories in which Allura Red AC is authorised. Updated information on the actual use levels of Allura Red AC (E 129) in foods was made available by FoodDrinkEurope (FDE), the International Chewing Gum Association (ICGA), Capsugel and the Association of the European Self-Medication Industry (AESGP). Data were provided for the following food categories: chewing gum (FCS 05.3); decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4 (FCS 05.4); fine bakery wares (FCS 07.2); casings and coatings and decorations for meat (FCS 08.2.3); flavoured drinks (FCS 14.1.4); and food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms (FCS 17.1).

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 for estimating exposure in the refined exposure scenarios (Section 3.1).

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

2.1.2.2. Summarised data on analytical results of Allura Red AC in foods from Member States

Analytical results from Member States were collected through the EFSA call for concentration data. Complete information on the methods of analysis was not made available to EFSA. In total, 4 975 analytical results were reported by seven countries: Germany (n = 3485), Slovakia (n = 673), Czech Republic (n = 317), Ireland (n = 208), Hungary (n = 144), Cyprus (n = 120) and Spain (n = 28). The data mainly related to flavoured drinks (FCS 14.1.4) and fine bakery wares (FCS 07.2). Foods were sampled between 2002 and 2013 and analysed during the same period of time. All the samples were analysed in accredited laboratories.

Some data received could not be taken into account (n = 1 205) and were excluded from the present exposure assessment. It could be owing to insufficiently described products or non-authorised products.¹⁴ Out of these, some data were reported on previously authorised products (e.g. smoked fishes, tomato-based sauces; n = 8). The analytical results were not detected (n = 708), not quantified (n = 384) and 113 were numerical values. It could be that these numerical values were on authorised

¹³ 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

¹⁴ Such results could be due to the use of multi-screening methods covering a large range of compounds from food control laboratories analysing the food samples and/or errors in the classification of the foods sampled and/or misuses.

food products but the description of the foods and their FCS code did not allow classifying them in an authorised food group. However, Allura Red AC (E 129) was detected in some not authorised products: compote (FCS 04.2.4.2), jam (FCS 04.2.5), cocoa and chocolate products (FCS 05.1), whole, broken or flaked grain (FCS 06.1), flours (FCS 06.2.1), starches (FCS 06.2.2), breakfast cereals (FCS 06.3), other sugars and syrups (FCS 11.2), fruit juices (FCS 14.1.2), fruit nectars (FCS 14.1.3), other alcoholic drinks (more than 15% of alcohol) (FCS 14.2.8) and processed foods (FCS 18).

Other samples (n = 100) were expressed as qualitative results (i.e. indication of the presence or absence of the food additive in the food analysed) and were also not used in the present assessment.

The remaining analytical data (n = 3 670) were on 35 food categories in which Allura Red AC (E 129) is authorised; therefore, for 16 food categories in which Allura Red AC (E 129) is authorised, no analytical data were available. Analytical results of Allura Red AC (E 129) were not detected (i.e. were below the limit of detection (LOD)) in 2 700 samples, and not quantified (i.e. were below the limit of quantification (LOQ)) in 325 samples. In 586 samples, quantified (numerical values) were available.

Out of these data, some analytical results (n = 12) exceeded the MPL for that food category, including one sample of ice cream (FCS 03), four samples of other confectionery including breath refreshing microsweets (FCS 05.2), one sample of fine bakery wares (FCS 07.2), one sample of fish roe (FCS 09.3), three samples of protein products (FCS 12.9) and two samples of flavoured drinks (FCS 14.1.4). Those samples were excluded from the present exposure assessment.

Overall, 3 658 analytical data were taken into account for the refined exposure assessment on Allura Red AC (E 129). For an overview of these data, see Appendix B.

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 data from national information on food consumption at a detailed level. Competent authorities in the 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 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 Allura Red AC (E 129)

The food categories in which the use of Allura Red AC (E 129) 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 therefore could not be taken into account in the present estimate. This resulted in an underestimation of the exposure. The

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food categories which were not taken into account are described below (in ascending order of FCS code):

- 01.7.3. Edible cheese rind
- 01.7.6. Cheese products (excluding products falling into category 16), only flavoured unripened products
- 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
- 08.1.1. Unprocessed meat other than meat preparations as defined by Regulation (EC) No 853/2004, only for the purpose of health marking
- 08.2.3. Casings and coatings and decorations for meat, only decorations and coatings except edible external coating of pasturmas
- 08.2.3. Casings and coatings and decorations for meat, only edible casings
- 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 (FCS 01.6 Cream and cream powder). The same applied in differentiating flavoured cream from plain cream. This food category was therefore also not taken into account in the present estimate.

For some food categories, no data were provided to EFSA and therefore could not be taken into account in the refined scenarios:

- 04.2.2. Fruit and vegetables in vinegar, oil, or brine, only preserves of red fruit
- 08.1.2. Meat preparations as defined by Regulation (EC) No 853/2004, only breakfast sausages
- 09.2. Processed fish and fishery products including molluscs and crustaceans, only precooked crustaceans
- 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).

It should be noted that, if Allura Red AC (E 129) is nevertheless used in those food categories, the calculated refined exposure assessment might result in underestimation of exposure to this food additive.

For the following food categories, the restrictions which apply to the use of Allura Red AC 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 the exposure:

- In the case of the food category 01.7.1, distinction between flavoured and non-flavoured foods is not possible within the EFSA Comprehensive Database.
- In the case of the food category 04.2.4.1, it is not possible to distinguish the foods defined under the restrictions applicable for the use of Allura Red AC (E 129), i.e. only preserves of red fruit.
- 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.
- 14.2.3, Cider and perry: no distinction was possible between cider and *cidre bouché*, therefore, the entire food category was accounted for in the exposure estimates.
- 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 of these food categories; therefore, the highest MPL and the highest use level reported within these categories were taken into account.
- 15.1, Potato-, cereal-, flour-, starch-based snacks: no distinction between savoury snacks (extruded, expanded or not) is possible within the FoodEx nomenclature; therefore, this food category was considered as a whole and the highest MPL and the highest use level reported within this food category were taken into account in the exposure estimates.
- 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, 16 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 became available to EFSA. Another 10 food categories were included in the exposure assessment without considering the restrictions as set in Annex II to Regulation No 1333/2008.

2.2. Methodologies

Dietary exposure to Allura Red AC (E 129) from its use as a food colour was estimated using the approach adopted by the Panel at its 52nd plenary meeting.¹⁵ 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. For calculation of chronic exposure, intake statistics have been calculated based on individual average consumption 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

¹⁵ http://www.efsa.europa.eu/en/events/event/140701a-m.pdf

and Exposure (EFSA, 2011a). High percentile exposure was calculated only for those foods and population groups where the sample size was sufficiently 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.

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

Table 3.	Population group	s considered for the exi	nosure estimates o	f Allura Red AC (F 129)
Table 5.	i opulation group	s constacted for the exp	posure estimates o	Γ Allula Keu AC (L 12)

(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 in the 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 exposure was calculated per survey for the total population and per population group.

Exposure assessment to Allura Red AC (E 129) 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) the availability of use levels or analytical data (defined as the *refined exposure assessment* scenario).

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 No 1333/2008 and listed in Table 2.

The exposure estimates derived following this scenario should be considered as the most conservative since they assume that the consumer will be continuously (over a lifetime) exposed to Allura Red AC present in the food at the MPLs. It should be noted however 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 should nevertheless 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. This refined exposure scenario can consider only food categories for which the above data were available.

Appendix C summarises the concentration levels of Allura Red AC (E 129) used in the refined exposure assessment scenario. Based on the available dataset, EFSA calculated two estimates based on different model populations:

- (1) <u>The brand-loyal consumer scenario</u>: This assumed that a consumer is exposed long term to the food additive present at the maximum reported use/analytical levels 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) <u>The non-brand-loyal consumer scenario</u>: This assumed that the population 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 scenarios, concentration levels considered were extracted from the whole dataset received (i.e. reported use levels and analytical results). To consider left-censored analytical data (i.e. analytical results < LOD or LOQ), the substitution method as recommended in the 'Principles and Methods for the Risk Assessment of Chemicals in Food' (WHO, 2009) and the EFSA scientific report 'Management of left-censored data in dietary exposure assessment of chemical substances' (EFSA, 2010b) was used. In the present opinion, analytical data below LOD or LOQ were assigned half of LOD or LOQ, respectively (middle bound (MB). 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 were available for the same food category, the most reliable value was used.

Food categories with no or inadequate reported use/analytical levels were not considered in the exposure assessment. EFSA noted that, if Allura Red AC (E 129) is nevertheless used in those food categories, the calculated refined exposure assessment might result in underestimation of exposure to this food additive.

3. Assessment

3.1. Exposure to Allura Red AC (E 129) from its use as a food additive

Table 4 summarises the anticipated exposure to Allura Red AC (E 129) 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 Allura Red AC (E 129) 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					
 Mean High level (95th percentile 	0.9–3.9	0.9–3.2	0.3–1.4	0.3–1.0	0.1–0.5
	2.8–6.7	1.9–6.4	0.9–3.1	0.8–2.4	0.5–1.1
Refined estimated exposure assessment scenario					
 Brand-loyal scenario Mean High level (95th percentile 	0.1–1.4	0.4–1.2	0.2–0.7	0.1–0.4	0.03–0.2
	0.4–2.7	0.9–2.9	0.7–2.1	0.4–1.2	0.1–0.6
 Non-brand-loyal scenario Mean High level (95th percentile 	0.03–0.6	0.1–0.5	0.1–0.3	0.02–0.2	0.01–0.1
	0.1–1.1	0.3–1.2	0.3–0.9	0.1–0.5	0.03–0.3

3.2. Main food categories contributing to exposure to Allura Red AC (E 129)

The main food categories contributing to total mean exposure to Allura Red AC (E 129) (> 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 Allura Red AC (E 129)using the regulatory maximum level exposure scenario (> 5 % of total exposure), and number ofsurveys to which each food category contributes

FCS	FCS food category	Toddlers	Children	Adolescents	Adults	The elderly	
category number		Range of % contribution to the total exposure (number of surveys) ^(a)					
01.4	Flavoured fermented milk products including heat-treated products	6.7–78.4 (7)	8.2–39.8 (13)	5.5–17.7 (9)	5–40.6 (13)	8.6–42.4 (6)	
1.7.1	Unripened cheese excluding products falling into category 16	5.1–9.2 (5)	7.1–17.2 (3)	18.1 (1)	5.1–26.3 (6)	5.2–28.5 (6)	
03	Edible ices	5–17.2 (3)	5.2–14 (12)	5.1-10.5 (5)	5–7.6 (4)	6.0–7.2 (3)	
05.2	Other confectionery including breath freshening microsweets		5.7–12.1 (5)	8.1–11 (2)	10.8– 10.9 (2)	7.2–7.3 (2)	
07.2	Fine bakery wares	11.1–55.3 (6)	12.8–48 (13)	15–43.7 (11)	6.3–40 (14)	13.4–46.7 (6)	
09.2	Processed fish and fishery products including molluscs and crustaceans			5.4 (1)	5.4–5.9 (3)		



FCS	FCS food category	Toddlers	Children	Adolescents	Adults	The elderly					
category number		Range of % contribution to the total exposure (number of surveys) ^(a)									
12.5	Soups and broths	6.4	5.2–18.6 (3)	17.4	6.4–25.3 (3)	11.1–22.2 (2)					
14.1.4	Flavoured drinks	5.8–41.8 (5)	12–57 (15)	24.4–67.9 (12)	14.8– 64.5 (15)	5.5–52.7 (7)					
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts					9.6–10.1 (2)					
15.1	Potato-, cereal-, flour- or starch-based snacks	5.9–7.5 (2)	5.0 (1)	5.4–10.9 (4)	5.4 (1)	5.9–10.8 (2)					
16	Desserts excluding products covered in categories 1, 3 and 4	13.2–16 (2)	5.2–11 (5)	5.6-8.7 (2)	5.5–7.5 (2)	6.7 (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 Allura Red AC (E 129)using the brand-loyal refined exposure scenario, (> 5 % of total exposure) and number of surveys towhich each food category contributes

FCS		Toddlers	Children	Adolescents	Adults	The elderly
category number	FCS food category	Rar	nge of % con (Nu	ntribution to th mber of survey	e total expo vs) ^(a)	sure
01.4	Flavoured fermented milk products including heat- treated products	10.9 (1)				
03	Edible ices	7.3–27 (4)	6.3–28.3 (7)	6.9–13.6 (3)	6.2–12.1 (4)	6.3–20 (3)
05.2	Other confectionery including breath freshening microsweets	9.7	5.4–21.9 (2)	5.7 (1)	7.0–27.7 (2)	8–21.9 (2)
07.2	Fine bakery wares	17.2–85.2 (7)	9.5–81.2 (14)	23.8–79.3 (11)	7.5–79.6 (14)	23.4–88.1 (6)
12.5	Soups and broths		5.4	5.2 (1)	8.0 (1)	7.9 (1)
14.1.4	Flavoured drinks	17.3–67.4 (5)	7.4–86.4 (15)	15.7–91.1 (12)	13.1– 82.4 (15)	7.1–65.2 (6)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts					13
16	Desserts excluding products covered in categories 1, 3 and 4	7.7–11.8 (2)	5.2 (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.

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Table 7: Main food categories contributing to the total mean exposure to Allura Red AC (E 129) using the non-brand loyal refined exposure scenario, (> 5 % of total exposure) and number of surveys to which each food category contributes

FCS category		Toddlers	Children	Adolescents	Adults	The elderly						
number	FCS food category	Range of % contribution to the total exposure (Number of surveys) ^(a)										
01.4	Flavoured fermented milk products including heat-treated products	13.6 (1)										
05.2	Other confectionery including breath freshening microsweets		8.2 (1)		8.7 (1)	7.1 (1)						
07.2	Fine bakery wares	33.8–91.8 (7)	12–87.7 (15)	9.4–77 (12)	16.8–80.7 (14)	39.3– 91.1 (6)						
09.3	Fish roe					5.0 (1)						
12.5	Soups and broths	5.8 (1)	10.6 (1)	10.1 (1)	5.3–14.3 (2)	6–14.9 (2)						
14.1.4	Flavoured drinks	13.8–56.7 (5)	9.7–77.8 (15)	19.8–83.9 (12)	15.2–75 (15)	6.5–56.3 (6)						
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts					5.3–13.6 (2)						
16	Desserts excluding products covered in categories 1, 3 and 4	6.2–9 (2)										
17	Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children					8.8 (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.

3.3. Discussion

EFSA has performed a refined exposure assessment for Allura Red AC (E 129) taking into consideration (1) the MPLs set down in the EU legislation (defined as *the regulatory maximum level exposure assessment* scenario); and (2) the availability of newly submitted data on its actual uses by industry and analytical data reported by Member States.

To date, EFSA has used the maximum concentration value (maximum reported use level or maximum value from the analytical results) available for each authorised food category to assess the dietary exposure to food additives. However, given the extensive range of usage/analytical data that have been made available through the most recent calls, EFSA considered that these data should also be used in additional scenarios of the exposure assessment approach intended to provide more realistic exposure estimates. This was agreed by the Panel at its 52nd plenary meeting.¹⁶

Based on the available dataset, two refined exposure estimates based on different assumptions were calculated: a *brand-loyal consumer* scenario, in which it was assumed that the population is exposed long term to the food additive present at the maximum reported use/analytical levels 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 scenario, in which it was assumed that the population is exposed long-term to the food additive present at the mean reported use/analytical levels for the remaining food categories; and a non-brand-loyal scenario, in which it was assumed that the population is exposed long-term to the food additive present at the mean reported use/analytical levels in the food.

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

Overall, exposure estimates derived following the regulatory maximum level exposure assessment scenario should be considered to be the most conservative estimates as this scenario assumes that the consumer will be continuously (over a lifetime) exposed to a food additive present in the food at the MPLs. The refined exposure assessment approach is considered a more realistic scenario, since it is based on the extensive range of concentration data and assumes that the processed foods and beverages contain the additive at the mean concentration level for all products (non-brand-loyal consumer scenario) and considers one product containing the food additive at the maximum concentration level (brand-loyal consumer scenario). In the refined exposure assessment scenario, food categories with no reported usage/analytical levels are not considered in the exposure assessment.

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 = 10) 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, unprocessed meat only for the purpose of health marking, casing and coating and decorations for meat, fruit wine and made wine (Appendix C). It is expected that not including these 10 food categories in the exposure assessment would have a negligible effect on the exposure estimates reported here. The same applies to the five food categories with no analytical data or usage levels. On the other side, for other food categories, the restrictions which apply to the use of Allura Red AC could not be taken into account and the whole food category was considered for the exposure estimates, resulting in an overestimation.

Despite these restrictions regarding the linkage between usage/analytical data and the FoodEx food groups, the food consumption data used in the present assessment was 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 Allura Red AC (E 129) in those items is not authorised. This resulted in having a more precise estimation of the exposure.

Concentration data were received either from industry (usage data) or from Member States (analytical data). Reported usages covered six food categories, while analytical levels covered 35 food categories. Finally 35 out of the 51 food categories in which Allura Red AC (E 129) is authorised were taken into account in the present assessment (Appendix C). The data submitted recently to EFSA were generally lower than those considered in the 2009 exposure assessment. This was true for e.g. flavoured milk products, seasonings and condiments, soups, sauces and alcoholic drinks, some of which contributed largely to the total mean exposure (EFSA ANS Panel, 2009). Higher usage levels than those provided in 2009 were reported only for flavoured processed cheese. It should be noted that 12 analytical results on foods in which Allura Red is authorised exceeded the MPL, and that the food additive was quantified in several foods in which Allura Red in not authorised.

Using the regulatory maximum level exposure assessment scenario, mean exposure to Allura Red AC (E 129) from its use as a food additive ranged from 0.1 mg/kg bw per day for the elderly to 3.9 mg/kg bw per day for toddlers. The high level exposure to Allura Red AC (E 129) using this scenario ranged from 0.5 to 6.7 mg/kg bw per day, respectively, for the same population groups. The main food categories contributing to the total mean exposure estimates for all populations in this scenario were flavoured drinks, fine bakery wares and flavoured fermented milk products. Mean estimates were in the same order of magnitude as those estimated in the 2009 opinion (EFSA ANS Panel, 2009), whereas, for toddlers, children, adolescents and the elderly, high-level estimates for Allura Red AC (E 129) are due to the more detailed available consumption data since most of the authorised foods and their MPLs remained the same as in 2009. New consumption data and the refinements in the selection of food items within the FoodEx nomenclature may contribute to a lower high level exposure. 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 Allura Red AC (E 129) in 2009 (EFSA ANS Panel, 2009), but the food categories used in the previous assessment were

broader than those available now in FoodEx. 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. The use of consumption data at individual level using refined food codes could also have contributed to the decrease in the estimates of exposure to Allura Red AC (E 129) resulting from its use as a food additive. Moreover, for adults, only UK consumption data were available, retrieved from UNESDA report (Tennant, 2006).

Using the refined brand-loyal assessment exposure scenario, mean exposure to Allura Red AC (E 129) from its use as a food additive ranged from 0.03 mg/kg bw per day for the elderly to 1.4 mg/kg bw per day for toddlers. The high level exposure to Allura Red AC (E 129) ranged from 0.1 mg/kg bw per day for the elderly to 2.9 mg/kg bw per day for children. The main food categories contributing to the total mean exposure estimates for all populations in this scenario were flavoured drinks and fine bakery wares.

Using the refined non-brand-loyal assessment exposure scenario, mean exposure to Allura Red AC (E 129) from its use as a food additive ranged from 0.01 mg/kg bw per day for the elderly to 0.6 mg/kg bw per day for toddlers. The high exposure to Allura Red AC (E 129) using this scenario ranged from 0.03 mg/kg bw per day for the elderly to 1.2 mg/kg bw per day for children. The main contributing food categories for all populations were fine bakery wares and flavoured drinks.

Exposure estimates based on usage/analytical levels were considerably lower at the mean and high exposure levels, for both children and adults, in the current assessment compared to the 2009 opinion (EFSA ANS Panel, 2009). However, an accurate comparison with the previous assessment is not possible owing to different approaches taken. In the 2009 assessment, the exposure calculation was based on maximum usage/analytical levels and MPLs replacing the missing usage/analytical levels for majority of food categories, while in the current assessment besides maximum usage/analytical levels also mean of typical usage/analytical levels were used and the food categories for which no usage/analytical value was available were not included in the assessment (Appendix C). Therefore, it should be noted that, if Allura Red AC (E 129) is nevertheless used in the food categories not considered in the exposure to Allura Red AC (E 129). EFSA also noted that the refined exposure estimates will not cover future changes in the level of use of Allura Red AC (E 129).

The overall estimates of the present exposure assessment were lower than those from the previous exposure assessment performed by the ANS Panel in 2009 (EFSA ANS Panel, 2009), and none exceeded the ADI of 7 mg/kg bw per day established for Allura Red AC (E 129).

3.4. 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 already been presented in the sections above and are summarised below.

Sources of uncertainties	Direction ^(a)
Consumption data: different methodologies/representativeness/underreporting/	1/
misreporting/no portion size standard	+/-
Use of data from food consumption survey of 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	
Use of MPLs in exposure assessment (regulatory maximum level exposure scenario)	+
Concentration data: no information on use/analytical data available for 5 food	
categories (refined estimated exposure scenario)	—

Table 8:Qualitative evaluation of influence of uncertainties



Sources of uncertainties	Direction ^(a)
MPLs and concentration data (reported use or analytical levels) considered applicable for all items within the entire food category	+
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	+/
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 Allura Red AC (E 129) and concluded that overall, uncertainty could lead to an overestimation of the calculated exposure estimates.

4. Conclusions

The current exposure estimates for Allura Red AC (E 129) provide an update of the exposure assessment performed in 2009 (EFSA ANS Panel, 2009).

In comparison with the previous assessment, the current exposure estimates for Allura Red AC (E 129) based on the MPLs scenario were in the same order of magnitude at the mean exposure level in all population groups, whereas high exposure levels (95th percentile) were lower for all populations except adults. Based on the refined scenarios, the current estimates were lower for all populations at both the mean and high exposure level.

Data received on Allura Red AC (E 129), reported either by industry or Member States, covered the majority of the authorised uses of Allura Red AC (E 129) as a food additive. However, no additional information was provided to EFSA for some food categories, which were therefore not taken into account in the refined scenarios. Concentration data of Allura Red AC (E 129) in foods used in the current estimates were generally lower than the data used in the ANS Panel opinion in 2009.

EFSA concluded that, using MPLs (regulatory maximum level exposure assessment scenario), exposure estimates were lower than those from the previous opinion of the ANS Panel in 2009 (EFSA, ANS Panel, 2009) and did not exceed the ADI of 7 mg/kg bw per day in any population. This was also true for the refined exposure scenarios based on usage/analytical levels at both the mean and high exposure level.

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APPENDICES

Appendix A.	Summary of reported	use levels of Allura l	Red AC (E 129)	provided by	industry (mg/	L or mg/kg as	appropriate)
							·····

FCS category	FCS food category	MPL	Restrictions/ exceptions	Number of data	Reporte from	d use levels industry	Information provided by	Comments
number					Typical mean (range)	Highest maximum level		
05.3	Chewing gum	300		1	17	280	ICGA	Only a proportion of chewing gum contains this food additive, and even less contains it at the maximum reported level. Part of the colour would not be ingested as captured in the gum cud which is disposed of after chewing (retention rate may vary)
05.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	500	Only decorations, coatings and sauces, except fillings	1	350	500	FDE	
07.2	Fine bakery wares	200		1	100	200	FDE	
08.3.3	Casings and coatings and decorations for meat	QS	Only edible casings	2	2	3	FDE	
14.1.4	Flavoured drinks	100	Excluding chocolate	17	24	75	FDE	Other flavoured drinks
			milk; malt products	5 (NP)	20	20	FDE	Cola drinks
17.1	Food supplements supplied in a	300		2	0.5	1	Capsugel	Empty capsule shell of 96 mg
	solid form including capsules and tablets and similar forms excluding chewable forms				50	50	AESGP	Use level expressed as mg/kg in the drink after dissolving the effervescent tablet in 200 mL of water

NP=Niche products

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В



				% of	L	OD	L	OQ	A	ll data (mi	ddle bou	nd)		Ро	sitive valu	es	
FCS category number	Food category	MPL	no of data	left- censored data	min	max	min	max	min	median	mean	max	No of positive values	min	median	mean	max
01.4	Flavoured fermented milk products including heat-treated products	150	5	100.0	0.0	8.0	0.0	8.0	0.0	0.3	0.9	4.0					
01.6.3	Other creams	150	1	0.0	0.0	0.0	0.1	0.1	35.0	35.0	35.0	35.0	1	35.0	35.0	35.0	35.0
01.7.1	Unripened cheese excluding products falling into category 16	150	1	100.0	0.2	0.2	0.5	0.5	0.3	0.3	0.3	0.3					
03	Edible ices	150	244	93.0	0.0	20.0	0.0	60.0	0.0	0.0	3.2	144.0	17	0.1	33.3	40.5	144.0
04.2.1	Dried fruit and vegetables	200	49	24.5	0.0	20.0	0.0	60.0	0.0	33.0	38.5	154.0	37	0.6	38.0	50.7	154.0
04.2.3	Canned or bottled fruit and vegetables	200	41	97.6	0.6	20.0	0.6	60.0	0.3	10.0	6.8	73.0	1	73.0	73.0	73.0	73.0
04.2.4.1	Fruit and vegetable preparations excluding compote	200	10	100.0	0.7	20.0	3.5	60.0	0.4	10.0	6.1	10.0					
05.2	Other confectionery including breath refreshening microsweets – except candied fruit and vegetables	300	779	57.5	0.0	20.0	0.0	60.0	0.0	10.0	18.7	278.4	331	0.1	18.4	37.5	278.4
05.2	Other confectionery including breath refreshening microsweets – only candied fruit and vegetables	200	97	52.6	0.0	20.0	0.0	60.0	0.0	4.2	19.7	120.0	46	0.2	34.4	39.6	120.0
05.3	Chewing gum	300	31	64.5	0.0	20.0	0.1	60.0	0.1	10.0	16.4	170.0	11	4.7	22.0	35.4	170.0
05.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4 – only decorations, coatings and sauces except fillings	500	55	72.7	0.2	20	0.7	60	0.4	2.5	36.2	351.0	15	37.0	79.8	124.7	351.0
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4 – only fillings	300	1	0.0					25.0	25.0	25.0	25.0	1	25.0	25.0	25.0	25.0
07.2	Fine bakery wares	200	864	99.0	0.0	20.0	0.1	60.0	0.3	10.0	8.9	27.0	9	0.3	4.0	6.6	27.0
08.3.2	Heat-treated processed meat	25	4	75.0	0.2	0.3	0.5	5.0	0.3	0.3	3.2	12.0	1	12.0	12.0	12.0	12.0
09.2	Processed fish and fishery products including molluscs and crustaceans	500	4	100.0	0.0	0.5	0.0	1.0	0.0	0.5	0.4	0.5					
09.3	Fish roe	300	10	10.0	0.0	0.2	0.0	0.5	0.0	169.0	154.9	283.3	9	76.0	171.7	172.1	283.3

Appendix B. Summary of analytical results of Allura Red AC (E 129) provided by Member States (mg/L or mg/kg as appropriate)

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				% of	L	OD	L	OQ	A	ll data (mi	ddle bou	nd)	Positive values				
FCS category number	Food category	MPL	Total no of data	left- censored data	min	max	min	max	min	median	mean	max	No of positive values	min	median	mean	max
12.2.2	Seasonings and condiments	500	7	100.0	0.7	20.0	3.5	60.0	0.4	10.0	7.2	10.0					
12.4	Mustard	300	2	100.0	0.2	0.2	0.5	0.5	0.3	0.3	0.3	0.3					
12.5	Soups and broths	50	11	100.0	0.2	20.0	0.5	60.0	0.3	10.0	7.5	10.0					
12.6	Sauces	500	35	97.1	0.0	20.0	0.0	60.0	0.0	10.0	8.5	58.7	1	58.7	58.7	58.7	58.7
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	50	25	100.0	0.0	20.0	0.0	60.0	0.0	10.0	7.4	10.0					
14.1.4	Flavoured drinks	100	1129	90.1	0.0	20.0	0.0	60.0	0.0	0.5	4.9	87.9	112	0.1	26.0	27.1	87.9
14.2.3	Cider and perry	200	4	100.0	0.5	10.0	1.0	10.0	0.3	2.7	2.7	5.0					
14.2.4	Fruit wine and made wine	200	45	97.8	0.0	20.0	0.1	60.0	0.1	0.4	2.5	10.0	1	1.8	1.8	1.8	1.8
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	200	41	56.1	0.0	20.0	0.1	60.0	0.0	5.0	18.1	83.0	18	1.0	32.0	38.4	83.0
14.2.7.1	Aromatised wines	200	5	100.0	0.0	1.0	0.0	3.0	0.0	0.0	0.2	0.5					
14.2.7.2	Aromatised wine-based drinks	100	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	200	34	97.1	0.0	20.0	0.0	60.0	0.0	0.1	1.8	17.4	1	17.4	17.4	17.4	17.4
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol	200	28	82.1	0.0	20.0	0.0	60.0	0.0	0.4	14.9	130.1	5	42.0	67.1	71.9	130.1
15.1	Potato-, cereal-, flour- or starch- based snacks	100	2	100.0	20.0	20.0	60.0	60.0	10.0	10.0	10.0	10.0					
15.2	Processed nuts	100	35	100.0	0.2	1.0	0.5	7.0	0.1	3.0	2.5	3.5					
16	Desserts excluding products covered in categories 1, 3 and 4	150	54	94.4	0.0	131.3	0.0	131.3	0.0	10.0	9.7	66.0	3	43.0	50.4	53.1	66.0
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms	300	1	0.0					43.0	43.0	43.0	43.0	1	43.0	43.0	43.0	43.0
17.2	Food supplements supplied in a liquid form	100	2	100.0	0.2	0.8	0.5	2.4	0.3	0.3	0.3	0.4					
17.3	Food supplements supplied in a syrup-type or chewable form	100	1	100.0	0.2	0.2	0.5	0.5	0.3	0.3	0.3	0.3					

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Appendix C. Concentration levels of Allura Red AC (E 129) used in the refined exposure scenarios (mg/L or mg/kg as appropriate)

FCS category number	FCS food category	Restrictions	MPL	Concer levels the r expo asses	ntration used in efined osure sment	Comments
				Max	Mean	
01.4	Flavoured fermented milk products including heat treated products		150	4	0.3	Analytical data
01.6.3	Other creams	Only flavoured creams	150	_	_	Not taken into account (overestimation by using FoodEx codes)
01.7.1	Unripened cheese excluding products falling into category 16	Only flavoured unripened cheese	150	0.3	0.3	Analytical data
01.7.3	Edible cheese rind		QS	_	_	Not taken into account (no corresponding FoodEx codes/no data reported)
01.7.6	Cheese products (excluding products falling into category 16)	only flavoured unripened products	100	_	_	Not taken into account (no corresponding FoodEx codes/no data reported)
03	Edible ices		150	144	3	Analytical data
04.2.1	Dried fruit and vegetables	Only preserves of red fruit	200	154	39	Analytical data
04.2.2	Fruit and vegetables in vinegar, oil, or brine	Only preserves of red fruit	200	_	_	Not taken into account (no data reported)
04.2.3	Canned or bottled fruit and vegetables	Only preserves of red fruit	200	73	7	Analytical data
04.2.4.1	Fruit and vegetable preparations excluding compote	Only <i>mostarda di frutta</i>	200	_	_	Not taken into account (no corresponding FoodEx codes/no data reported)
04.2.4.1	Fruit and vegetable preparations excluding compote	Only preserves of red fruit	200	10	6	Analytical data
05.2	Other confectionery including breath refreshening microsweets	Except candied fruit and vegetables	300	278	19	Analytical data
05.2	Other confectionery including breath refreshening microsweets	Only candied fruit and vegetables	200	120	20	Analytical data
05.3	Chewing gum		300	280	17	Reported use levels



FCS category number	FCS food category	Restrictions	MPL	Concer levels the r expe	ntration used in efined osure sment	Comments
				Max	Mean	
05.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	Only decorations, coatings and sauces, except fillings	500	_	_	Not taken into account (no corresponding FoodEx codes)
05.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	Only fillings	300	_	-	Not taken into account (no corresponding FoodEx codes)
06.6	Batters	Only batters for coating	500	_	_	Not taken into account (no corresponding FoodEx codes)
07.2	Fine bakery wares		200	200	100	Reported use levels
08.1	Unprocessed meat other than meat preparations as defined by Regulation (EC) No 853/2004	Only for the purpose of health marking	QS	_	_	Not taken into account (no corresponding FoodEx codes)
08.2	Meat preparations as defined by Regulation (EC) No 853/2004	Only breakfast sausages with a minimum cereal content of 6 % and burger meat with a minimum vegetable and/or cereal content of 4 % mixed within the meat. In these products, the meat is minced in such a way that the muscle and fat tissue are completely dispersed, so that fibre makes an emulsion with the fat, giving those products their typical appearance	25		_	Not taken into account (no corresponding FoodEx codes/no data reported)
08.3.2	Heat-treated processed meat	Only <i>luncheon meat</i>	25	12	3	Analytical data
08.3.3	Casings and coatings and decorations for meat	only decorations And coatings except edible external coating of <i>pasturmas</i>	500		_	Not taken into account (no corresponding FoodEx codes)
08.3.3	Casings and coatings and decorations for meat	only edible casings	QS	_	_	Not taken into account (no corresponding FoodEx codes)
09.2	Processed fish and fishery products including molluscs and crustaceans	Only surimi and similar products and salmon substitutes	500	0.5	0.4	Analytical data



FCS category number	FCS food category	Restrictions	MPL	Concer levels the re expo	ntration used in efined osure sment	Comments
				Max	Mean	
09.2	Processed fish and fishery products including molluscs and crustaceans	Only precooked crustaceans	250	_	_	Not taken into account (no data reported)
09.3	Fish roe	Except sturgeons' eggs (caviar)	300	283	155	Analytical data
12.2.2	Seasonings and condiments	Only seasonings, for example curry powder, tandoori	500	10	7	Analytical data
12.4	Mustard		300	0.3	0.3	Analytical data
12.5	Soups and broths		50	10	8	Analytical data
12.6	Sauces	Including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces	500	59	9	Analytical data
12.9	Protein products, excluding products covered in category 1.8	only meat and fish analogues based on vegetable proteins	100	-	-	Not taken into account (no data reported)
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)		50	10	7	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)		50	_	_	Not taken into account (no data reported)
14.1.4	Flavoured drinks	Excluding chocolate milk; malt products	100	20	20	Reported use levels—for cola drinks
				88	24	Reported use levels—for other flavoured drinks
14.2.3	Cider and perry	Excluding <i>cidre bouché</i>	200	5	3	Analytical data
14.2.4	Fruit wine and made wine	Excluding wino owocowe mark	200	_	_	Not taken into account (no corresponding FoodEx codes)



FCS category number	FCS food category	Restrictions	MPL	Concentration levels used in the refined exposure assessment		Concentration levels used in the refined exposure assessment		Comments
				Max	Mean			
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	200	83	18	Analytical data		
14.2.7.1	Aromatised wines	Except <i>americano</i> , <i>bitter vino</i>	200	17	2	Analytical data		
14.2.7.1	Aromatised wines	Only bitter vino	100					
14.2.7.2	Aromatised wine-based drinks	Except bitter soda, sangria, claria, zurra	200					
14.2.7.2	Aromatised wine-based drinks	Only bitter soda	100					
14.2.7.3	Aromatised wine-product cocktails		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 and nalewka na winie owocowym, aromatyzowana nalewka na winie owocowym, nalewka na winie z soku winogronowego, aromatyzowana nalewka na winie z soku winogronowego, napój winny owocowy lub miodowy, aromatyzowany napój winny owocowy lub miodowy, wino owocowe niskoalkoholowe and aromatyzowane wino owocowe niskoalkoholowe	200	130	15	Analytical data		
15.1	Potato-, cereal-, flour- or starch-based snacks	Excluding extruded or expanded savoury snack products	100	10	10	Analytical data		
15.1	Potato-, cereal-, flour- or starch-based snacks	Only extruded or expanded savoury snack products	200					



FCS category number	FCS food category	Restrictions	MPL	Concentration levels used in the refined exposure assessment		Comments
15.0	D 1		100	Max	Mean	
15.2	Processed nuts	Only savoury coated nuts	100	4	3	Analytical data
16	Desserts excluding products covered in categories 1, 3 and 4		150	66	10	Analytical data
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms		300	50	25	Reported use levels
17.2	Food supplements supplied in a liquid form		100			
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			



Appendix D. Summary of total estimated exposure of Allura Red AC (E 129) 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	MPL scenario		Brand-loyal scenario		Non brand-loyal	
	of subjects	Mean	High level	Mean	High level	Mean	High
Toddlers						icver	
Belgium (Regional Flanders)	36	3.9		1.4		0.6	
Bulgaria (NUTRICHILD)	428	1.1	2.8	0.8	1.9	0.4	1.0
Germany (DONALD 2006 2008)	261	1.0	2.8	0.5	1.5	0.2	0.5
Spain (enKid)	17	1.4		0.3		0.2	
Finland (DIPP 2003 2006)	497	0.9	3.1	0.1	0.4	0.0	0.1
Italy (INRAN SCAI 2005 06)	36	0.9		0.3		0.2	
Netherlands (VCP kids)	322	3.1	6.7	1.0	2.7	0.4	1.1
Children							
Belgium (Regional Flanders)	625	3.2	6.4	1.2	2.9	0.5	1.2
Bulgaria (NUTRICHILD)	433	1.4	3.5	1.0	2.3	0.5	1.2
Czech Republic (SISP04)	389	1.7	4.0	0.9	2.5	0.4	1.0
Germany (DONALD 2006 2008)	660	1.6	3.8	0.8	2.0	0.3	0.7
Denmark (Danish Dietary Survey)	490	1.3	2.6	0.7	1.5	0.2	0.5
Spain (enKid)	156	1.3	3.3	0.6	1.4	0.2	0.7
Spain (NUT INK05)	399	1.2	2.7	0.5	1.2	0.2	0.6
Finland (DIPP 2003 2006)	933	1.2	2.8	0.4	0.9	0.1	0.3
Finland (STRIP)	250	1.8	3.2	0.9	1.7	0.4	0.8
France (INCA2)	482	1.6	3.2	0.8	1.6	0.4	0.9
Greece (Regional Crete)	839	1.1	2.3	0.6	1.4	0.3	0.7
Italy (INRAN SCAI 2005 06)	193	0.9	1.9	0.5	1.1	0.2	0.6
Latvia (EFSA TEST)	189	1.1	2.5	0.6	1.6	0.3	0.8
Netherlands (VCP kids)	957	2.8	5.9	0.9	2.1	0.4	1.0
Sweden (NFA)	1473	2.5	4.8	1.1	2.3	0.5	1.0
Adolescents							
Belgium (Diet National 2004)	584	1.2	2.5	0.5	1.3	0.3	0.6
Cyprus (Childhealth)	303	0.3	0.9	0.2	0.7	0.1	0.3
Czech Republic (SISP04)	298	1.2	3.1	0.7	2.1	0.3	0.9
Germany (National Nutrition Survey II)	1011	0.7	2.2	0.4	1.2	0.2	0.6
Denmark (Danish Dietary Survey)	479	1.0	2.3	0.6	1.5	0.2	0.5
Spain (AESAN FIAB)	86	0.5	1.3	0.3	0.7	0.1	0.3
Spain (enKid)	209	0.8	2.0	0.4	1.2	0.2	0.5
Spain (NUT INK05)	651	0.7	1.6	0.3	0.8	0.2	0.4
France (INCA2)	973	0.8	1.8	0.4	1.0	0.2	0.5
Italy (INRAN SCAI 2005 06)	247	0.6	1.4	0.3	0.7	0.1	0.4
Latvia (EFSA TEST)	470	0.7	1.8	0.4	1.1	0.2	0.5
Sweden (NFA)	1018	1.4	3.0	0.7	1.5	0.3	0.6



	Number	MPL scenario		Brand-loyal scenario		Non brand-loyal scenario	
	of subjects	Mean	High level	Mean	High level	Mean	High level
Adults							
Belgium (Diet National 2004)	1304	0.8	2.0	0.3	1.0	0.2	0.5
Czech Republic (SISP04)	1666	0.5	1.3	0.3	0.9	0.1	0.4
Germany (National Nutrition Survey II)	10419	0.5	1.5	0.3	0.8	0.1	0.4
Denmark (Danish Dietary Survey)	2822	0.4	1.2	0.2	0.8	0.1	0.3
Spain (AESAN)	410	0.5	1.3	0.2	0.6	0.1	0.3
Spain (AESAN FIAB)	981	0.4	1.1	0.2	0.5	0.1	0.3
Finland (FINDIET 2007)	1575	0.3	1.0	0.1	0.4	0.0	0.1
France (INCA2)	2276	0.4	1.1	0.2	0.6	0.1	0.3
United Kingdom (NDNS)	1724	0.5	1.2	0.2	0.6	0.1	0.3
Hungary (National Repr Surv)	1074	0.3	0.9	0.1	0.5	0.1	0.2
Ireland (NSIFCS)	958	0.4	1.0	0.2	0.5	0.1	0.2
Italy (INRAN SCAI 2005 06)	2313	0.3	0.8	0.1	0.4	0.1	0.2
Latvia (EFSA TEST)	1306	0.4	0.9	0.2	0.6	0.1	0.3
Netherlands (DNFCS 2003)	750	1.0	2.4	0.4	1.2	0.2	0.5
Sweden (Riksmaten 1997 98)	1210	0.6	1.3	0.3	0.8	0.1	0.3
The elderly							
Belgium (Diet National 2004)	1230	0.5	1.1	0.2	0.6	0.1	0.3
Germany (National Nutrition Survey II)	2496	0.4	1.0	0.2	0.6	0.1	0.3
Denmark (Danish Dietary Survey)	329	0.2	0.6	0.1	0.3	0.0	0.1
Finland (FINDIET 2007)	463	0.1	0.5	0.0	0.1	0.0	0.0
France (INCA2)	348	0.3	0.7	0.1	0.4	0.1	0.2
Hungary (National Repr Surv)	286	0.2	0.7	0.1	0.5	0.1	0.2
Italy (INRAN SCAI 2005 06)	518	0.2	0.5	0.1	0.3	0.0	0.1



ABBREVIATIONS

ADI	Acceptable Daily Intake
AESGP	Association of the European Self-Medication Industry
ANS Panel	Scientific Panel on Food Additives and Nutrient Sources added to Food
bw	body weight
EC	European Commission
EFSA	European Food Safety Authority
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	Food Drink Europe
ICGA	International Chewing Gum Association
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOD	limit of detection
LOQ	limit of quantification
MB	middle bound
MPL	Maximum Permitted Level
QS	quantum satis
SCF	Scientific Committee for Food
UK	United Kingdom
UNESDA	Union of European Soft Drinks Associations
WHO	World Health Organization