

STATEMENT OF EFSA

Refined exposure assessment for Azorubine/Carmoisine (E 122)¹

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ABSTRACT

Following a self-tasking request, the European Food Safety Authority (EFSA) carried out a refined exposure assessment for Azorubine/Carmoisine (E 122) 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 Azorubine/Carmoisine (E 122) used as a food additive. In that opinion, the Panel concluded that, at the high percentile of exposure (95th), using either the maximum permitted levels (MPLs) or the reported use levels provided by industry, intake estimates for 1- to 10-year-old children could be above the Acceptable Daily Intake (ADI) of 4 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 Comprehensive European Food Consumption Database. Usage data from industry were provided to EFSA for five out of the 50 food categories in which Azorubine/Carmoisine (E 122) is authorised as a food additive, whereas analytical data from Member States were provided to EFSA for 32 food categories. Using MPLs, exposure estimates exceeded the ADI at the high level for toddlers and children. In the refined exposure scenarios, the ADI was not exceeded for any of the population groups at either the mean or the higher exposure level.

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KEY WORDS

Azorubine/Carmoisine, E 122, dietary exposure, EFSA Comprehensive European Food Consumption Database, food colours

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SUMMARY

Following a self-tasking request, the European Food Safety Authority (EFSA) carried out a refined exposure assessment for Azorubine/Carmoisine (E 122) 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 Azorubine/Carmoisine (E 122) used as a food additive. In that opinion, the Panel concluded that, at the high percentile of exposure (95th), using either the maximum permitted levels (MPLs) or the reported use levels provided by industry, intake estimates for 1- to 10-year-old children could be above the Acceptable Daily Intake (ADI) of 4 mg/kg body weight (bw) per day. Following this conclusion, EFSA carried out a refined exposure assessment for this colour, taking into account additional information on usage levels in foods, as well as analytical data submitted to EFSA by Member States.

Azorubine/Carmoisine (E 122) 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 1983 (JECFA, 1983a, b) and by the Scientific Committee for Food (SCF) in 1984 (SCF, 1984) and 1989. Both committees established an Acceptable Daily Intake (ADI) of 0–4 mg/kg bw.

In 2009, the ANS Panel re-evaluated Azorubine/Carmoisine (E 122) as a food additive. The safety of the use of Azorubine/Carmoisine (E 122) was assessed on the basis of uses and use levels authorised in legislation⁴ and of reported use levels, as provided by industry. Based on that assessment, the ANS Panel concluded that there was no reason to revise the ADI of 4 mg/kg bw per day.

The ANS Panel also concluded that at both the MPLs and the maximum reported use levels of Azorubine/Carmoisine (E 122), intake estimates for 1- to 10-year-old children at the high percentile (95th) could exceed the ADI of 4 mg/kg bw per day.

The present review provides a refined exposure assessment for Azorubine/Carmoisine (E 122) 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 Azorubine/Carmoisine (E 122) 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 Azorubine/Carmoisine (E 122) reported by industry covered five out of the 50 authorised uses of Azorubine/Carmoisine as a food additive, whereas analytical data received from Member States covered 32 food categories.

In comparison with the previous assessment, the current exposure estimates based on the MPL scenario were of the same order of magnitude, at both the mean and the high level, for all populations. However, based on the refined scenarios, the current estimates were lower for all populations at both the mean and the high exposure level, and did not exceed the ADI.

EFSA concluded that, using MPLs, exposure estimates exceeded the ADI of 4 mg/kg bw per day at the high level for toddlers and children. In the refined exposure scenarios, the ADI was not exceeded by any of the population groups.

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. Available online: <u>http://www.efsa.europa.eu/en/data/call/130327.htm</u>



TABLE OF CONTENTS

Abstract	1
Summary	2
1. Introduction	4
1.1. Background and Terms of reference as provided by EFSA	4
1.2. Interpretation of the Terms of Reference	5
1.3. Additional information	5
2. Data and methodologies	6
2.1. Data	6
2.1.1. Use and use levels of Azorubine/Carmoisine (E 122)	6
2.1.2. Reported use levels and analytical levels of Azorubine/Carmoisine (E 122) in foods	s 9
2.1.2.1. Summarised data on reported use levels of Azorubine/Carmoisine (E 122) in fe	oods
provided by industry	10
2.1.2.2. Summarised data on analytical levels of Azorubine/Carmoisine (E 122) in food	ds
provided by Member States	10
2.1.3. Food consumption	11
2.1.3.1. EFSA Comprehensive European Food Consumption Database	11
2.1.3.2. Food items selected for the refined exposure assessment of Azorubine/Carmois	sine
(E 122)	12
2.2. Methodologies	13
2.2.1. Regulatory maximum level exposure assessment scenario	14
2.2.2. Refined exposure assessment scenario	15
3. Assessment	16
3.1. Exposure to Azorubine/Carmoisine (E 122) from its use as a food additive	16
3.2. Main food categories contributing to exposure to Azorubine/Carmoisine (E 122)	16
3.3. Uncertainty analysis	19
3.4. Discussion	19
4. Conclusions	21
Documentation provided to EFSA	22
References	22
Appendices	24
Abbreviations	35



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 EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) in the opinions on the so-called Southampton colours (quinoline yellow,⁶ sunset yellow,⁷ ponceau 4R⁸). 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 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 Commission regulation (EU) No 1129/2011 of 11 November 2011 on amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives. OJ L 295, 12.11.2011, p. 1.



1.2. Interpretation of the Terms of Reference

The aim of the present statement is to provide a refined exposure assessment for Azorubine/Carmoisine (E 122) as a food colour using the exposure assessment approach adopted by the ANS Panel at its 52nd plenary meeting¹⁰ as part of the safety assessment of food additives under re-evaluation. The current exposure assessment 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

Azorubine/Carmoisine (E 122) is an azo dye allowed as a food additive in the EU and has been previously evaluated by the Joint Food and Agricultural Organization (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) in 1983 (JECFA, 1983a, b) and by the EU 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).

In 2009, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) re-evaluated Azorubine/Carmoisine (E 122) as a food additive (EFSA ANS Panel, 2009). The safety of the use of Azorubine/Carmoisine (E 122) 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 ADI of 4 mg/kg bw per day.

The ANS Panel concluded that at the maximum reported levels of use of Azorubine/Carmoisine (E 122), refined intake estimates are below the ADI, although, in 1- to 10-year-old children, the high percentile of exposure (95th) could be slightly higher than the ADI at the upper end of the range (Table 1).

The main contributors (> 10 %) to the total anticipated mean exposure of the adult population to Azorubine/Carmoisine (E 122) were non-alcoholic beverages (50 %) and sauces and seasonings (e.g. curry powder, tandoori), pickles, relishes, chutney, piccalilli (17 %). For children, the main contributing food categories were non-alcoholic beverages (17–65 %), fine bakery wares (e.g. Viennoiserie, biscuits, cakes, wafer) (10–34 %), desserts, including flavoured milk products, (15–42 %) and sauces, seasonings (e.g. curry powder, tandoori), pickles, relishes, chutney, piccalilli (15–70 %). Surimi accounted for 11 % of exposure in one country.

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.

Table 1: Summary of anticipated exposure to Azorubine/Carmoisine (E 122) in children and the adult UK population as calculated in the previous 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- to 10-year-olds, 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	0.7–6.7
Estimated exposure using reported use levels		
Mean exposure	0.4	0.3–2.4
Exposure 95th ^(b) or 97.5th percentile ^(a)	1.0	0.6–6.5

(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 11- to 14-year-old children Cypriot children, whose reported body weight was 54 kg.

2. Data and methodologies

2.1. Data

2.1.1. Use and use levels of Azorubine/Carmoisine (E 122)

Maximum permitted levels (MPLs) of Azorubine/Carmoisine (E 122) are defined in Annex II to Regulation (EC) No $1333/2008^{12}$ on food additives, as amended. The MPLs range from 50 to 500 mg/kg and are set at *quantum satis* (QS) in two food categories. In addition, Azorubine/Carmoisine (E 122) 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 Azorubine/Carmoisine (E 122) and the corresponding MPLs as set by Annex II to Regulation (EC) No 1333/2008.

Table 2:	MPLs of	Azorubine/Carmoisine	(E 122) i	n foods	according	to A	nnex I	I of	Regulation
(EC) No 13	33/2008								

FCS ^(a) category number	Food category	Restrictions/exception	E number/group	MPL (mg/L or mg/kg as appropriate)
01.4	Flavoured fermented milk products, including heat- treated products		Group III	150
01.6.3	Other creams	Only flavoured creams	Group III	150
01.7.1	Unripened cheese, excluding products falling in category 16	Only flavoured unripened cheese	Group III	150
01.7.3	Edible cheese rind		Group III	QS
01.7.5	Processed cheese	Only flavoured processed cheese	E 122	100
01.7.6	Cheese products (excluding products falling in category 16)	Only flavoured unripened products	Group III	100

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.

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FCS ^(a) category number	Food category	Restrictions/exception	E number/group	MPL (mg/L or mg/kg as appropriate)
03	Edible ices		Group III	50
04.2.1	Dried fruit and vegetables	Only preserves of red fruit	E 122	200
04.2.2	Fruit and vegetables in vinegar, oil or brine	Only preserves of red fruit	E 122	200
04.2.3	Canned or bottled fruit and vegetables	Only preserves of red fruit	E 122	200
04.2.4.1	Fruit and vegetable preparations, excluding compote	Only mostarda di frutta	Group III	200
04.2.4.1	Fruit and vegetable preparations, excluding compote	Only preserves of red fruit	E 122	200
05.2	Other confectionery, including breath refreshening microsweets	Except candied fruit and vegetables	Group III	50
05.2	Other confectionery, including breath refreshening microsweets	Only candied fruit and vegetables	Group III	200
05.3	Chewing gum		Group III	50
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	Only decorations, coatings and sauces, except fillings	Group III	500
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	Only fillings	Group III	50
06.6	Batters	Only batters for coating	Group III	500
07.2	Fine bakery wares		Group III	50
08.3.3	Casings and coatings and decorations for meat	Only decorations and coatings, except edible external coating of pastourmas	Group III	500
08.3.3	Casings and coatings and decorations for meat	Only edible casings	Group III	QS
09.2	Processed fish and fishery products, including molluscs and crustaceans	Only surimi and similar products and salmon substitutes	Group III	500
09.2	Processed fish and fishery products, including molluscs and crustaceans	Only fish paste and crustacean paste	E 122	100
09.2	Processed fish and fishery products, including molluscs and crustaceans	Only precooked crustacean	E 122	250
09.3	Fish roe	Except Sturgeons' eggs (caviar)	Group III	300
12.2.2	Seasonings and condiments	Only seasonings, for example curry powder, tandoori	Group III	500
12.4	Mustard		Group III	300
12.5	Soups and broths		Group III	50



FCS ^(a) category number	Food category	Restrictions/exception	E number/group	MPL (mg/L or mg/kg as appropriate)
12.6	Sauces	Including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces	Group III	500
12.9	Protein products, excluding products covered in category 1.8	Only meat and fish analogues based on vegetable proteins	Group III	100
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	Excluding chocolate milk; malt products	Group III	50
14.2.3	Cider and perry	Excluding cidre bouché	Group III	200
14.2.4	Fruit wine and made wine	Excluding wino owocowe markowe	Group III	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) 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	Group III	200
14.2.7.1	Aromatised wines	Except americano, bitter vino	Group III	200
14.2.7.1	Aromatised wines	Only americano, bitter vino	E 122	100
14.2.7.2	Aromatised wine-based drinks	Except bitter soda, sangria, claria, zurra	Group III	200
14.2.7.2	Aromatised wine-based drinks	Only bitter soda	E 122	100
14.2.7.3	Aromatised wine-product cocktails		Group III	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	Group III	200



FCS ^(a) category number	Food category	Restrictions/exception	E number/group	MPL (mg/L or mg/kg as appropriate)
		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	Excluding extruded or expanded savoury snack products	Group III	100
15.1	Potato-, cereal-, flour- or starch-based snacks	Only extruded or expanded savoury snack products	Group III	200
15.2	Processed nuts	Only savoury-coated nuts	Group III	100
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	Only solid food supplements	Group III	300
17.3	Food supplements supplied in a syrup-type or chewable form	Only liquid food supplements	Group III	100

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

2.1.2. Reported use levels and analytical levels of Azorubine/Carmoisine (E 122) in foods

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 for performing a more realistic exposure assessment, especially for those food additives for which no MPL is set and which are authorised according to QS.

In the framework of Regulation (EC) No 1333/2008 on food additives and of Commission Regulation (EU) No $257/2010^{13}$ regarding the re-evaluation of approved food additives, EFSA issued a public call¹⁴ for food additives concentration data (usage level and/or analytical data) on Azorubine/Carmoisine (E 122).

Data on Azorubine/Carmoisine (E 122), including present use and use patterns (i.e. the food categories and subcategories and the actual use levels (typical and maximum use levels), especially for those uses which are limited only by QS), were requested from relevant stakeholders. European food

¹³ Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 80, 26.3.2010, p. 19.

¹⁴ 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. Available online: <u>http://www.efsa.europa.eu/en/data/call/130327.htm</u>



manufacturers, national food authorities, research institutions, academia, food business operators and any other interested stakeholders were invited to submit analytical data on Azorubine/Carmoisine (E 122) in foods and beverages. Data submission to EFSA followed the requirements of the EFSA Guidance on Standard Sample Description for Food and Feed (EFSA, 2010a).

2.1.2.1. Summarised data on reported use levels of Azorubine/Carmoisine (E 122) in foods provided by industry

Industry provided EFSA with data on use levels (n = 25) of Azorubine/Carmoisine (E 122) in foods belonging to five out of the 50 food categories in which Azorubine/Carmoisine (E 122) is authorised. These data were provided by Food Drink Europe (FDE), the International Chewing Gum Association (ICGA), Capsugel and the Association of the European Self-Medication Industry (AESGP), and covered the following food categories: chewing gum (FCS 05.3); decorations, coatings and fillings, except fruit-based fillings covered by category 04.2.4 (FCS 05.4); sauces (FCS 12.6); flavoured drinks (FCS 14.1.4); and food supplements supplied in a solid form, including capsules, 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 were used, as well as the mean of the typical reported use levels per food category for estimating the exposure in the refined exposure assessment scenarios (Section 3.1).

Data provided by industry are summarised by food category in Appendix A.

2.1.2.2. Summarised data on analytical levels of Azorubine/Carmoisine (E 122) in foods provided by 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, 6 644 analytical results were reported by eight countries: Austria (n = 994), Cyprus (n = 194), the Czech Republic (n = 333), Germany (n = 3296), Hungary (n = 480), Ireland (n = 208), Slovakia (n = 1099) and Spain (n = 40). These data were mainly on flavoured drinks (FCS food category 14.1.4), other confectionery, including breath freshening microsweets (FCS food category 05.2), fine bakery wares (FCS food category 07.2) and edible ices (FCS 03). Foods were sampled between 2000 and 2013 and analysed during the same period of time. All samples came from accredited laboratories.

In order to include only recent data, analytical results sampled before 2004 (n = 18) were excluded from the exposure assessment. Moreover, 940 analytical results expressed as qualitative values were also not used, as they gave only an indication of the presence or absence of the food additive in the food analysed.

Food samples were codified by the Member States in accordance with the Food Classification System as in Regulation No 1333/2008, Annex II, Part D. A large number of samples (n = 1439) either were not codified in sufficient detail to allow them to be assigned to the correct authorised food category (e.g. FCS 14.1) or were codified with information resulting in the suggestion that Azorubine/Carmoisine (E 122) is present in non-authorised food categories; the latter, however, 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 between samples with a codification error and samples in which Azorubine/Carmoisine (E 122) was present in a food in which it is not authorised. These 1 439 samples were not used in the present exposure assessment. In most of the 1 439 samples, Azorubine/Carmoisine (E 122) was not detected or not quantified (below the limit of detection (LOD) or the limit of quantification (LOQ), respectively), but in others (n = 309) numerical values (i.e. with quantified levels of the food additive in food) were reported. These were mostly data on the food categories other sugars and syrups (FCS 11.2), non-alcoholic beverages (FCS 14.1, not specified), fruit juices (FCS 14.1.2), alcoholic beverages (FCS 14.2, not specified), spirit drinks (FCS 14.2.6, other than those defined under the restrictions which apply to the use of



Azorubine/Carmoisine), other alcoholic drinks, including mixtures of alcoholic drinks with nonalcoholic drinks and spirits with less than 15 % of alcohol (FCS 14.2.8, other than those defined under the restrictions which apply to the use of Azorubine/Carmoisine), jam, jellies and marmalades and similar products (FCS 04.2.5), other similar fruit or vegetables spreads (FCS 04.2.5.3) and cocoa and chocolate products (FCS 05.1).

Overall, 4 247 out of the 6 644 analytical results reported for Azorubine/Carmoisine (E 122) corresponded to food categories in which Azorubine/Carmoisine (E 122) is currently authorised. Out of this dataset, analytical results of Azorubine/Carmoisine (E 122) were not quantified (lower than the LOQ) in 498 samples and not detected (lower than the LOD) in 2 603 samples; 1 146 were numerical values (quantified).

Samples with numerical values covered mainly the following four food categories: flavoured drinks (FCS 14.1.4), other confectionery, including breath freshening microsweets (FCS 05.2), alcoholic beverages (FCS 14.2) and edible ices (FCS 03). Out of these samples, 32 contained levels of Azorubine/Carmoisine (E 122) above their MPLs: 18 samples of flavoured drinks; six of food supplements; two each of spirit drinks and edible ices; and one each of flavoured fermented milk products, including heat-treated products, other alcoholic drinks, including mixtures of alcoholic drinks with non-alcoholic drinks and spirits less than 15 % alcohol, candied fruit and vegetables and fine bakery wares. For the exposure assessment, EFSA considers analytical data resulting from only authorised uses at levels not exceeding the MPLs; exposure resulting from the presence of food additives in food at levels above the MPLs are part of risk management measures, e.g. non-compliance controls. For this reason, such analytical results above the MPLs are not considered in the exposure assessment.

Therefore, after removal of these 32 samples, 4 215 analytical results were available for the refined exposure assessment. These data covered 32 food categories out of the 50 in which Azorubine/Carmoisine (E 122) is authorised.

Appendix B shows the analytical results of Azorubine/Carmoisine (E 122) in foods as reported by Member States (whole set of analytical data reported and positive samples only) 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 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 comparisons 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 under-reporting 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, part D, to Regulation (EC) No 1333/2008, as amended, for the exposure assessment.



2.1.3.2. Food items selected for the refined exposure assessment of Azorubine/Carmoisine (E 122)

The food categories in which the use of Azorubine/Carmoisine (E 122) is authorised were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx classification system food codes), at the most detailed level possible (up to FoodEx Level 4) (EFSA, 2011b).

Some analysed food items are not referenced in the EFSA Comprehensive Database and could therefore not be taken into account in the present estimate. This resulted in an underestimation of the exposure to Azorubine/Carmoisine (E 122). The food categories 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
- 08.3.3 Casings and coatings and decorations for meat, only decorations and coatings except edible external coating of pastourmas
- 08.3.3 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 exposure assessment.

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

- 01.7.3 Edible cheese rind
- 01.7.6 Cheese products (excluding products falling into category 16), only flavoured unripened products
- 04.2.2 Fruit and vegetables in vinegar, oil, or brine, only preserves of red fruit
- 04.2.4.1 Fruit and vegetable preparations excluding compote, only mostarda di frutta
- 06.6 Batters
- 08.3.3 Casings and coatings and decorations for meat, only decorations and coatings, except edible external coating of pastourmas
- 08.3.3 Casings and coatings and decorations for meat, only edible casings
- 09.2 Processed fish and fishery products, including molluscs and crustaceans, only surimi and similar products and salmon substitutes
- 09.2 Processed fish and fishery products, including molluscs and crustaceans, only fish paste and crustacean paste



- 09.2 Processed fish and fishery products, including molluscs and crustaceans, only precooked crustaceans
- 09.3 Fish roe, except sturgeon's eggs (caviar)
- 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).

Nevertheless, it should be noted that if Azorubine/Carmoisine (E 122) is used in these food categories, the calculated refined exposure assessment results in an underestimation of exposure to this food additive.

For the following food categories, the restrictions which apply to the use of Azorubine/Carmoisine (E 122) could not be taken into account, and therefore the whole food category was considered in the exposure assessment. This results 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 04.2.2, it is not possible to distinguish the foods defined under the restrictions applicable for the use of Azorubine/Carmoisine (E 122), i.e. only preserves of red fruit.
- 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 in 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 analytical level 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, 17 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 or analytical data were available to EFSA. Another nine food categories were included in the exposure assessment without considering the restrictions for the use of Azorubine/Carmoisine (E 122) as set in Annex II to Regulation No 1333/2008.

2.2. Methodologies

Dietary exposure to Azorubine/Carmoisine (E 122) from its use as a food colour was estimated using the approach adopted by the Panel at its 52nd plenary meeting¹⁵. This approach is to be followed to assess exposure as part of the safety assessment of food additives under re-evaluation, making use of food consumption data available within the EFSA Comprehensive Database, as presented in Table 3, and with the limitations described below.

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

EFSA estimated chronic exposure to Azorubine/Carmoisine (E 122) for the following population groups: toddlers, children, adolescents, adults and the elderly. For the assessment, food consumption data were available from 26 different dietary surveys carried out in 17 different European countries (Table 3). Calculations were performed using individual body weights. For calculation of chronic exposure, intake statistics have been calculated based on individual consumption over the total survey period, excluding surveys with only one day per subject, which are considered inadequate to assess chronic dietary exposure, as suggested by the EFSA Working Group on Food Consumption and Exposure (EFSA, 2011a).

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	groups	considered	for	the	exposure	estimates	of	Azorubine/Carmoisine
(E 122)									

(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).

To estimate the exposure, FoodEx food codes were matched to the FCS food categories and the exposure was subsequently 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 survey days per individual, resulting in an individual average exposure per day for the survey period. This was carried out 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.

High percentile exposure was calculated only for population groups in which 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.

Exposure assessment to Azorubine/Carmoisine (E 122) 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).

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, as amended, 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 Azorubine/Carmoisine (E 122) present in the foods at the MPLs. It should be noted, however, as described in Section 2.1.3.2, that some food items could not be taken into account in the present exposure assessment for all scenarios, including two food categories with QS (Table 2). This should, nevertheless, represent a minor underestimation of the exposure calculated with this scenario.

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 calculates two estimates based on different model populations:

- (1) <u>The brand-loyal consumer scenario</u>: This scenario assumes 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 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 scenarios, concentration levels considered are extracted from the whole dataset received (i.e. reported use levels and analytical results). Regarding analytical results, in considering 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) is used. Analytical data below the LOD or LOQ are assigned half of the LOD or LOQ value, respectively (medium bound (MB)). 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 Azorubine/Carmoisine (E 122), 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 Azorubine/Carmoisine (E 122) were not considered in the exposure assessment. EFSA noted that, if Azorubine/Carmoisine (E 122) 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 Azorubine/Carmoisine (E 122) from its use as a food additive

Table 4 summarises the anticipated exposure to Azorubine/Carmoisine (E 122) 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 Azorubine/Carmoisine (E 122) from its use as a food additive according to the regulatory maximum level exposure scenario and the refined exposure scenarios in five population groups (minimum–maximum across the dietary surveys in mg/kg bw per day)

	Toddlers (12–35	Children (3–9 years)	Adolescents (10–17	Adults (18–64	The elderly (> 65 years)				
	months)		years)	years)					
Regulatory maximum level exposure assessment scenario									
Mean	0.5-2.6	0.5-2.2	0.2-0.8	0.2–0.6	0.1-0.3				
High level (95th percentile)	1.4–5.7	1.1-4.8	0.4–1.7	0.5–1.4	0.4-0.8				
Refined estimated exposure assessm	nent scenario								
Brand-loyal scenario									
• Mean	0.1-0.9	0.1–0.7	0.1-0.4	0.04-0.3	0.02-0.1				
• High level (95th percentile)	0.2–1.9	0.3–1.7	0.3-1.0	0.2–0.9	0.1-0.4				
Non-brand-loyal scenario									
• Mean	0.03-0.6	0.1-0.4	0.05-0.2	0.02-0.2	0.01-0.1				
• High level (95th percentile)	0.1-0.9	0.2-1.1	0.2–0.6	0.1-0.5	0.03-0.2				

3.2. Main food categories contributing to exposure to Azorubine/Carmoisine (E 122)

The main food categories contributing to total mean exposure to Azorubine/Carmoisine (E 122) (> 5 % of total exposure) according to the regulatory maximum level exposure assessment 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 Azorubine/Carmoisine (E 122) using the regulatory maximum level exposure assessment scenario (> 5 % of total exposure), and number of surveys in which each food category contributes

FCS	FCS food category	Toddlers	Children	Adolescents	Adults	The
category						elderly
number		Rai	nge of % contri	bution to the to	tal exposure	e
			(numb	er of surveys) ^{(a})	
01.4	Flavoured fermented	14.9-86.4	14.4–59.9	5.6-33.2	7.1–54.0	7.8–49.8
	milk products, including	(7)	(13)	(10)	(14)	(7)
	heat-treated products					
01.7.1	Unripened cheese,	5.6-13.9 (6)	5.6-30.6	5.2-32.0	6.0–39.9	5.0-41.7
	excluding products		(7)	(4)	(9)	(7)
	falling in category 16					
01.7.5	Processed cheese	12.8-13.8				7.8
		(2)				(1)
03	Edible ices	9.1	5.6-8.2	6.2		
		(1)	(7)	(1)		
07.2	Fine bakery wares	8.0-30.9 (3)	5.3-29.0	7.0-21.6	5.8-18.3	5.2-20.4
			(12)	(11)	(12)	(6)



FCS category	FCS food category	Toddlers	Children	Adolescents	Adults	The elderly
number		Ra	nge of % contri (numb	ibution to the to	tal exposur	е
09.2	Processed fish and fishery products, including molluses and crustaceans			7.1–10.6 (2)	5.3–11.6 (5)	6.1–7.1 (2)
12.4	Mustard				6.6 (1)	6.2 (1)
12.5	Soups and broths	9.6 (1)	6.2–32.3 (5)	6.4–29.7 (4)	5.0-40.4 (5)	19.4–32.9 (2)
14.1.4	Flavoured drinks	13.8–31.2 (5)	10.8–52.5 (15)	21.6–66.2 (12)	11.2– 55.1 (15)	7.7–44.8 (5)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts				5.2–9.3 (4)	11.3–15.6 (2)
15.1	Potato-, cereal-, flour- or starch-based snacks	6.0–16.8 (2)	5.9–9.8 (6)	5.4–23.1 (7)	7.3–9.9 (4)	
16	Desserts, excluding products covered in categories 1, 3 and 4	6.0–17.8 (3)	5.1–19.3 (7)	8.0–17.1 (3)	7.7–13.3 (3)	6.5–17.8 (3)
17	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children					7.9 (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 Azorubine/Carmoisine (E 122) using the brand-loyal refined exposure scenario (> 5 % of total exposure), and number of surveys in 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	7.4–38.8 (3)	5.1 (1)		5.0 (1)						
01.7.5	Processed cheese	6.6–9.5 (2)									
03	Edible ices	12.3–23.5 (3)	6.1–18.2 (6)	6.3–12.9 (2)	5.1–12.3 (2)	6.3–15.6 (2)					
07.2	Fine bakery wares	8.0–32.4 (4)	5.3-32.6 (10)	7.1–17.7 (9)	7.0–23.9 (10)	6.6-40.8 (5)					
12.5	Soups and broths	5.3–5.9 (2)	5.6–14.1 (2)	12.8 (1)	5.2–20.4 (2)	12.7–18.4 (2)					
14.1.4	Flavoured drinks	11.5–79.6 (6)	26.8–93.8 (15)	44.7–95.2 (12)	33.3–91.8 (15)	14.1–84.5 (7)					
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts				5.7–17.1 (5)	31.6–34.2 (2)					



FCS	FCS food category	Toddlers	Children	Adolescents	Adults	The elderly						
category number		Range of % contribution to the total exposure (number of surveys) ^(a)										
15.1	Potato-, cereal-, flour- or starch-based snacks	11.0–28.3 (4)	5.3–21.6 (8)	8.5–29.3 (5)	5.4–11.5 (6)							
16	Desserts, excluding products covered in categories 1, 3 and 4	8.0–53.0 (3)	6.0–38.6 (9)	5.4–25.8 (5)	5.9–25.0 (5)	17.4–49.2 (3)						
17	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children					18.1 (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 7: Main food categories contributing to the total mean exposure to Azorubine/Carmoisine (E 122) using the non-brand-loyal refined exposure scenario (> 5 % of total exposure), and number of surveys in which each food category contributes

FCS	FCS food category	Toddlers	Children	Adolescents	Adults	The elderly
category number			Range of % c	ontribution to t umber of surve	he total exposur ys) ^(a)	e.
01.4	Flavoured fermented milk products, including heat-treated products	5.4–32.9 (4)	5.2–6.4 (2)		5.5 (1)	6.3 (1)
01.7.5	Processed cheese	19.5–25.8 (2)				10.0 (1)
03	Edible ices	5.6–10.3 (2)	5.5–7.9 (3)	5.1 (1)	5.1 (1)	6.3 (1)
07.2	Fine bakery wares	8.0–33.4 (5)	5.5–31.9 (11)	7.2–20.0 (9)	5.1-22.2 (11)	5.2-41.6 (6)
12.5	Soups and broths	8.8–12.0 (2)	6.6–27.1 (5)	5.6–25.0 (3)	8.7–38.9 (3)	27.8–35.1 (2)
14.1.4	Flavoured drinks	13.2–80.0 (6)	40.6–92.5 (15)	52.5–94.6 (12)	37.8–93.9 (15)	27.9–88.6 (7)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts				5.3–7.5 (2)	17.0–19.4 (2)
15.1	Potato-, cereal-, flour- or starch-based snacks	7.4–10.2 (2)	5.4 (1)	6.6–7.0 (2)		
16	Desserts, excluding products covered in categories 1, 3 and 4	14.6–30.6 (2)	5.7-11.8 (4)	7.9 (1)	7.8 (1)	19.4 (1)
17	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children					11.1 (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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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 already been presented in the sections above and are summarised below.

Table 8: Quali	tative evaluation	of influence of	f uncertainties
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Sources of uncertainties	Direction ^(a)
Consumption data: different methodologies/representativeness/under-	. /
reporting/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	
MPLs and concentration data (reported use or analytical levels) considered applicable for	
all items within the entire food category	Ŧ
Regulatory maximum level exposure scenario: Use of MPLs in exposure assessment	+
Regulatory maximum level exposure scenario: food categories authorised at QS not	
considered in the scenario (2 / 50 food categories)	—
Refined estimated exposure scenario: food categories not taken into account (because of	
no use/analytical data available for the food category or food category not available within	—
FoodEx nomenclature)	
Refined estimated exposure scenario: not addressing results in non-authorised food	
categories (n = 309 values)	—
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	1/-

(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 Azorubine/Carmoisine (E 122) 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 Azorubine/Carmoisine (E 122) 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 *refined exposure assessment* scenario).

This second exposure assessment scenario was based on the dataset available for 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 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 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 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 = 9) 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, casings and coatings and decorations for meat and fruit wine and made wine (Appendix C). It is expected that not including these nine food categories in the exposure assessment would have a negligible effect on the exposure estimates reported here. The same applies to the seven food categories (e.g. fish roe, surimi and similar products and salmon substitutes) for which no analytical data or usage levels were available and that were therefore not considered in the exposure assessment. However, for some food categories, the restrictions which apply to the use of Azorubine/Carmoisine (E 122) 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 linkage between the food categories for which usage/analytical data were provided and the FoodEx food groups coded in the Comprehensive Database, food consumption data used in the present assessment were more detailed than 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 Azorubine/Carmoisine (E 122) in those items is not authorised. Exclusion of non-relevant food subgroups resulted in 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 five food categories, whereas analytical levels covered 32 food categories out of the 50 food categories in which Azorubine/Carmoisine (E 122) is authorised. Finally, 33 food categories were taken into account in the present exposure assessment (Appendix C). The food additive concentration values submitted to EFSA were generally lower than those considered in the 2009 exposure assessment. This was true for, for example, 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 for only flavoured processed cheese. According to analytical data, Azorubine/Carmoisine (E 122) was detected in several food categories for which industry did not report any use level (e.g. edible ices, other confectionery, fine bakery wares, alcoholic drinks, such as spirit drinks, alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks, snacks (potato-, cereal-, flouror starch-based snacks), desserts. However, Azorubine/Carmoisine (E 122) was not detected in sauces although use was reported by industry. Finally, it should be noted that 32 analytical results of foods in which Azorubine/Carmoisine (E 122) is authorised exceeded the MPL, and that the food additive was quantified in several foods in which Azorubine/Carmoisine (E 122) is not authorised. These data were not included in the calculations, and may potentially have resulted in an underestimation of the exposure.

Using the *regulatory maximum level exposure assessment* scenario, mean exposure to Azorubine/Carmoisine (E 122) from its use as a food additive ranged from 0.1 mg/kg bw per day for the elderly, to 2.6 mg/kg bw per day for toddlers. The high level exposure using this scenario ranged from 0.4 to 5.7 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 fermented milk products and flavoured drinks.

These exposure estimates were a bit lower than, but of the same order of magnitude as, those reported in the 2009 ANS opinion on Azorubine/Carmoisine (E 122); e.g. high-level estimates in children. The difference in outcome is very likely due to the use of more detailed consumption data, since the foods in which the use of Azorubine/Carmoisine (E 122) is authorised and the respective MPLs were the

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same as in 2009. New consumption data and the refinements in the selection of food items within the FoodEx nomenclature may have contributed to lower exposure estimates. Indeed, some of the consumption surveys of children currently included in the EFSA Comprehensive Database were also used in the 2009 ANS opinion (EFSA ANS Panel, 2009), but the food categories in the previous assessment were broader than those presently available in FoodEx. 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. Overall, the use of consumption data at individual level using more refined food codes has very likely resulted in the decrease in exposure to Azorubine/Carmoisine (E 122) using MPLs. Moreover, for adults, only UK consumption data were available, retrieved from a UNESDA report (Tennant, 2006).

Using the *refined brand-loyal exposure assessment* scenario, mean exposure to Azorubine/Carmoisine (E 122) from its use as a food additive ranged from 0.02 mg/kg bw per day for the elderly to 0.9 mg/kg bw per day for toddlers, whilst the high-level exposure ranged from 0.1 mg/kg bw per day to 1.9 g/kg bw per day, respectively. The main food category contributing to the total mean exposure estimates for all populations in this scenario was flavoured drinks and, to a lesser extent, fine bakery wares and desserts.

Using the *refined non-brand-loyal exposure* assessment scenario, mean exposure to Azorubine/Carmoisine (E 122) 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, whilst the high-level exposure ranged from 0.03 mg/kg bw per day for the elderly to 1.1 mg/kg bw per day for children. The main contributing food category for all populations was flavoured drinks and, to a lesser extent, fine bakery wares.

Compared with the 2009 ANS opinion (EFSA ANS Panel, 2009), the current refined brand-loyal scenario exposure estimates were lower for all populations (at both the mean and the high exposure levels). The refined non-brand-loyal scenario exposure estimates (at both the mean and the high level) were considerably lower than 2009 exposure estimates, up to six times lower for children at the high level. 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 were used to replace the missing usage/analytical levels for the majority of the food categories, while in the current assessment, besides maximum reported use/analytical levels, the mean of typical reported use/analytical levels were also used, and the food categories for which no use/analytical value was available were not included in the assessment (Appendix C). Therefore, it should be noted that if, nevertheless, Azorubine/Carmoisine (E 122) is used in the food categories not considered in this exposure assessment, the calculated refined exposure estimates might result in a underestimation of exposure to Azorubine/Carmoisine (E 122). It can also be noted that fine bakery wares contributed up to 40 % in some surveys whereas no uses were reported by industry and the food additive was detected in few analytical samples (29 out of 891). Finally, EFSA noted that the refined exposure estimates will not cover future changes in the levels of use of Azorubine/Carmoisine (E 122).

Overall, the refined exposure estimates in the present assessment were lower than those from the previous exposure assessment performed by the ANS Panel in 2009 (EFSA ANS Panel, 2009), and did not exceed the ADI of 4 mg/kg bw per day established for Azorubine/Carmoisine (E 122).

4. Conclusions

The current exposure estimates for Azorubine/Carmoisine (E 122) 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 Azorubine/Carmoisine (E 122) based on the MPL scenario were generally of the same order of magnitude, despite being a bit lower at the high-level exposure for toddlers and children. In the refined exposure scenarios, the current estimates were lower for all populations at both the mean and the high exposure level.

Concentration data received on Azorubine/Carmoisine (E 122), either from industry or from Member States, covered the majority of the authorised uses of Azorubine/Carmoisine (E 122) as a food additive. However, no information was made available to EFSA for some food categories, which were therefore not taken into account in the refined exposure scenarios. The concentration data for Azorubine/Carmoisine (E 122) in foods used in the current estimates were lower than the data used in the 2009 ANS opinion for some of the main contributing food categories (fine bakery wares, flavoured fermented milk products).

EFSA noted that, applying the conservative scenario based on the MPLs (regulatory maximum level exposure assessment scenario), exposure estimates exceeded the ADI of 4 mg/kg bw per day at the high level (95th percentile) for toddlers and children. When using the more realistic refined exposure assessment approaches, the ADI was not exceeded by any population.

DOCUMENTATION PROVIDED TO EFSA

- 1. Data on usage levels of Azorubine/Carmoisine (E 122). September 2013. Submitted by FoodDrinkEurope (FDE).
- 2. Data on usage levels of Azorubine/Carmoisine (E 122). September 2013. Submitted by the International Chewing Gum Association (ICGA).
- 3. Data on usage levels of Azorubine/Carmoisine (E 122). July 2013. Submitted by Capsugel.
- 4. Data on usage levels of Azorubine/Carmoisine (E 122). September 2013. Submitted by the Association of the European Self-Medication Industry (AESGP).

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APPENDICES

Appendix A. Summary of reported use levels of Azorubine/Carmoisine (E 122) provided by industry (mg/L or mg/kg as appropriate)

FCS category number	FCS food category	MPL	Restrictions/exceptions	Number of data	Reported from i	d use levels industry	Information provided by
					Typical mean (range)	Highest maximum level	
05.3	Chewing gum	50		1	28.6	50.0	ICGA
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	50.0	100.0	FDE
12.6	Sauces	500	Including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces	2	62.0	254.0	FDE
14.1.4	Flavoured drinks	50	Excluding chocolate milk; malt products	19	27.8	48.0	FDE
17.1	Food supplements supplied in a solid	300		1	0.5	1.9	Capsugel
	form, including capsules and tablets and similar forms, excluding chewable forms			1	25.0	25	AESGP

183



FCS	FCS Food category	MPL	n	%	Range	e LOD	Range	e LOQ All data			Positive values						
category No				LC	Min	Max	Min	Max	Min	Median	Mean	Max	n	Min	Median	Mean	Max
01.4	Flavoured fermented milk products, including heat- treated products	150	9	66.7	0.0	8.0	0.1	8.0	0.3	0.9	2.0	6.2	3	0.8	0.9	2.6	6.2
01.6.3	Other creams	150	7	14.3	0.0	0.2	0.1	0.5	0.3	17.4	21.9	43.8	6	0.8	24.5	25.5	43.8
01.7.1	Unripened cheese, excluding products falling in category 16	150	3	100.0	0.2	0.2	0.5	2.0	0.3	1.0	0.8	1.0					
01.7.5	Processed cheese	100	1	100.0	20.0	20.0	60.0	60.0	10.0	10.0	10.0	10.0					
03	Edible ices	50	266	74.8	0.0	20.0	0.0	60.0	0.0	1.5	6.6	49.9	67	0.1	20.2	23.7	49.9
04.2.1	Dried fruit and vegetables	200	6	100.0	0.2	0.2	1.2	1.2	0.1	0.1	0.1	0.1					
04.2.3	Canned or bottled fruit and vegetables	200	36	100.0	0.2	20.0	0.6	60.0	0.1	10.0	5.6	10.0					
04.2.4.1	Fruit and vegetable preparations, excluding compote – only preserve of red fruits	200	14	92.9	0.2	20.0	0.5	60.0	0.1	5.5	5.2	10.0	1	0.6	0.6	0.6	0.6
05.2	Other confectionery, including breath freshening microsweets – except candied fruit and vegetables	50	765	73.7	0.0	20.0	0.1	60.0	0.1	2.5	5.9	48.0	201	0.1	8.6	11.8	48.0
05.2	Other confectionery, including breath freshening microsweets – only candied fruit and vegetables	200	49	98.0	0.0	20.0	0.1	60.0	0.1	0.3	1.3	10.0	1	9.7	9.7	9.7	9.7
05.3	Chewing gum	50	38	57.9	0.0	20.0	0.1	60.0	0.1	8.3	9.9	49.3	16	0.6	13.7	16.4	49.3
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	50	43	90.7	0.2	20.0	0.7	60.0	0.1	1.0	4.9	20.4	4	9.0	9.5	12.1	20.4
07.2	Fine bakery wares	50	891	96.7	0.0	20.0	0.0	60.0	0.0	10.0	8.6	31.0	29	0.1	2.5	4.6	31.0
12.2.2	Seasonings and condiments	500	7	100.0	0.2	20.0	1.2	60.0	0.1	10.0	7.2	10.0					
12.4	Mustard	300	6	100.0	0.2	0.2	0.5	5.0	0.3	2.5	1.8	2.5					

Appendix B. Summary of analytical results of Azorubine/Carmoisine (E 122) provided by Member States (mg/L or mg/kg as appropriate)

18314732, 201



FCS	FCS Food category	MPL	n	%	Range	e LOD	Range	e LOQ	All data				Positive values				
category No				LC	Min	Max	Min	Max	Min	Median	Mean	Max	n	Min	Median	Mean	Max
12.5	Soups and broths	50	11	100.0	0.2	20.0	0.5	60.0	0.1	10.0	7.4	10.0					
12.6	Sauces	500	33	100.0	0.2	20.0	1.2	60.0	0.1	10.0	7.5	10.0					
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	50	31	100.0	0.2	20.0	1.2	60.0	0.1	10.0	7.3	10.0					
14.1.4	Flavoured drinks	50	1502	65.7	0.0	20.0	0.0	60.0	0.0	4.0	8.2	50.0	515	0.1	16.5	19.3	50.0
14.2.3	Cider and perry	200	7	71.4	0.0	10.0	0.1	10.0	0.1	5.0	9.6	24.0	2	23.0	23.5	23.5	24.0
14.2.4	Fruit wine and made wine	200	127	54.3	0.0	20.0	0.1	60.0	0.1	9.8	15.7	139.6	58	2.0	21.0	29.8	139.6
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	200	118	12.7	0.0	20.0	0.1	60.0	0.1	13.5	35.8	200.0	103	0.2	20.0	40.6	200.0
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	18	100.0	0.2	20.0	0.6	60.0	0.1	5.0	4.2	10.0					
14.2.8	Other alcoholic drinks, including mixtures of alcoholic drinks with non- alcoholic drinks and spirits with less than 15 % of alcohol	200	75	68.0	0.0	20.0	0.1	60.0	0.0	5.0	9.7	102.0	24	0.3	10.5	23.9	102.0
15.1	Potato-, cereal-, flour- or starch-based snacks excluding extruded or expanded savoury snack products	100	17	76.5	2.0	20.0	6.0	60.0	3.0	3.0	12.7	67.0	4	11.0	42.7	40.8	67.0
15.1	Potato-, cereal-, flour- or starch-based snacks —only extruded or expanded savoury snack products	200	29	55.2	0.0	1.7	0.1	6.0	2.1	3.0	20.7	199.0	13	2.1	8.0	42.4	199.0
16	Desserts, excluding products covered in categories 1, 3 and 4	150	50	66.0	0.2	20.0	0.7	60.0	0.1	10.0	14.8	136.2	17	0.7	24.8	32.5	136.2

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FCS FCS Food category		MPL	MPL n %		Rang	Range LOD J		Range LOQ		All data			Positive values				
category No				LC	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	300	6	33.3	2.0	2.0	6.0	6.0	1.0	13.6	64.6	274.0	4	6.1	52.9	96.5	274.0
17.2	Food supplements supplied in a liquid form	100	1	100.0	0.8	0.8	2.4	2.4	0.4	0.4	0.4	0.4					
17.3	Food supplements supplied in a syrup-type or chewable form	300	1	100.0	2.0	2.0	6.0	6.0	1.0	1.0	1.0	1.0					
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					

%LC, percentage of left-censored data; Max, maximum; Min, minimum; n, number of data.

18314732, 20



FCS ^(a) Food category M		MPL	Restrictions/exception	Concer	tration	Data sources/
category number				levels us refined o assess	ed in the exposure sment	comments
				Mean	Max	
01.4	Flavoured fermented milk products, including heat- treated products	150		2	6.2	Analytical data
01.6.3	Other creams	150	Only flavoured creams	_	_	Not taken into account (no corresponding FoodEx code)
01.7.1	Unripened cheese, excluding products falling in category 16	150	Only flavoured unripened cheese	1	1	Analytical data
01.7.3	Edible cheese rind	QS		_	_	Not taken into account (no corresponding FoodEx code/no analytical data or reported use levels)
01.7.5	Processed cheese	100	Only flavoured processed cheese	10	10	Analytical data
01.7.6	Cheese products (excluding products falling in category 16)	100	Only flavoured unripened products	_	_	Not taken into account (no corresponding FoodEx code/no analytical data or reported use levels)
03	Edible ices	50		7	50	Analytical data
04.2.1	Dried fruit and vegetables	200	Only preserves of red fruit	0.1	0.1	Analytical data
04.2.2	Fruit and vegetables in vinegar, oil or brine	200	Only preserves of red fruit	_	_	Not taken into account (no analytical data or reported use levels)
04.2.3	Canned or bottled fruit and vegetables	200	Only preserves of red fruit	10	10	Analytical data
04.2.4.1	Fruit and vegetable preparations, excluding compote	200	Only <i>mostarda di frutta</i>	_	_	Not taken into account (no corresponding FoodEx code/no analytical data or reported use levels)
04.2.4.1	Fruit and vegetable preparations, excluding compote	200	Only preserves of red fruit	6	10	Analytical data

Appendix C. Concentration levels of Azorubine/Carmoisine (E 122) used in the refined exposure scenarios (mg/L or mg/kg as appropriate)



FCS ^(a) category number	Food category	MPL	Restrictions/exception	Concer levels us refined o assess Mean	ntration ed in the exposure sment Max	Data sources/ comments
05.2	Other confectionery, including breath refreshening microsweets— except candied fruit and vegetables	50		6	48	Analytical data
05.2	Other confectionery, including breath refreshening microsweets— only candied fruit and vegetables	200		1	10	Analytical data
05.3	Chewing gum	50		29	50	Reported use levels
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 code)
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4— only fillings	50		_	_	Not taken into account (no corresponding FoodEx code)
06.6	Batters	500	Only batters for coating	-	-	Not taken into account (no corresponding FoodEx code/no analytical data or reported use levels)
07.2	Fine bakery wares	50		9	31	Analytical data
08.3.3	Casings and coatings and decorations for meat	500	Only decorations and coatings except edible external coating of pastourmas	_	_	Not taken into account (no corresponding FoodEx code/no analytical data or reported use levels)
08.3.3	Casings and coatings and decorations for meat	QS	Only edible casings	-	-	Not taken into account (no corresponding FoodEx code/no analytical data or reported use levels)



FCS ^(a) category number	Food category	MPL	Restrictions/exception	Concen levels us refined e assess Mean	ntration ed in the exposure sment Max	Data sources/ comments
09.2	Processed fish and fishery, products including molluscs and crustaceans	500	Only surimi and similar products and salmon substitutes	_	_	Not taken into account (no analytical results or reported use levels)
09.2	Processed fish and fishery products, including molluscs and crustaceans	100	Only fish paste and crustacean paste	_	_	Not taken into account (no analytical results or reported use levels)
09.2	Processed fish and fishery products, including molluscs and crustaceans	250	Only precooked crustacean	_	_	Not taken into account (no analytical results or reported use levels)
09.3	Fish roe	300	Except Sturgeon eggs (caviar)	_	_	Not taken into account (no analytical results or reported use levels)
12.2.2	Seasonings and condiments	500	Only seasonings, for example curry powder, tandoori	10	10	Analytical data
12.4	Mustard	300		2.5	2.5	Analytical data
12.5	Soups and broths	50		10	10	Analytical data
12.6	Sauces	500	Including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces	62	254	Reported use levels
12.9	Protein products, excluding products covered in category 1.8	100	Only meat and fish analogues based on vegetable proteins	_	_	Not taken into account (no analytical results 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)	50		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)	50		_	_	Not taken into account (no analytical results or reported use levels)



FCS ^(a) category number	Food category	MPL	Restrictions/exception	Concentration levels used in the refined exposure assessment Mean Max		Data sources/ comments
14.1.4	Flavoured drinks	50	Excluding chocolate milk; malt products	28	50	Combination of reported use levels and analytical data
14.2.3	Cider and perry	200	Excluding cidre bouché	10	24	Analytical data
14.2.4	Fruit wine and made wine	200			_	Not taken into account (no corresponding FoodEx code)
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	200	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	36	200	Analytical data
14.2.7.1	Aromatised wines	200	Except americano, bitter vino	5	10	Analytical data
14.2.7.1	Aromatised wines	100	Only americano, bitter vino			
14.2.7.2	Aromatised wine- based drinks	200	Except <i>bitter soda, sangria, claria, zurra</i>			
14.2.7.2	Aromatised wine- based drinks	100	Only bitter soda			
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	200	Only alcoholic drinks with less than 15 % of alcohol	10	102	Analytical data
15.1	Potato-, cereal-, flour- or starch- based snacks	100	Excluding extruded or expanded savoury snack products	18	199	Analytical data
15.1	Potato-, cereal-, flour- or starch- based snacks	200	Only extruded or expanded savoury snack products			
15.2	Processed nuts	100	Only savoury coated nuts	_	_	Not taken into account (no analytical results or reported use levels)



FCS ^(a) category number	Food category	MPL	Restrictions/exception	Concentration levels used in the refined exposure assessment		Data sources/ comments
				Mean	Max	
16	Desserts, excluding products covered in categories 1, 3 and 4	150		15	136	Analytical data
17.1	Food supplements supplied in a solid form, including capsules and tablets and similar forms, excluding chewable forms	300		44	274	Analytical data
17.2	Food supplements supplied in a liquid form	100				
17.3	Food supplements supplied in a syrup-type or chewable form	300	Only solid food supplements			
17.3	Food supplements supplied in a syrup-type or chewable form	100	Only liquid food supplements			

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

Appendix D. Summary of total estimated exposure of Azorubine/Carmoisine (E 122) from its use as a food additive for the regulatory maximum level exposure scenario (MPL scenario) and the refined exposure scenarios per population group and survey: mean and high level (mg/kg bw per day)

	Number of	MPLs scenario		Brand-loyal scenario		Non-brand-loyal scenario	
	subjects	Mean	High level	Mean	High level	Mean	High level
Toddlers							
Belgium (Regional Flanders)	36	2.6	_ ^(a)	0.9	_(a)	0.6	_ ^(a)
Bulgaria (NUTRICHILD)	428	0.5	1.4	0.2	0.7	0.1	0.4
Germany (DONALD 2006 2008)	261	0.6	2.1	0.2	0.6	0.1	0.3
Spain (enKid)	17	1.3	_(a)	0.3	_ ^(a)	0.1	_ ^(a)
Finland (DIPP 2003 2006)	497	0.8	2.9	0.1	0.2	0.0	0.1
Italy (INRAN SCAI 2005 06)	36	0.7	_ ^(a)	0.1	_ ^(a)	0.0	_ ^(a)
Netherlands (VCP kids)	322	2.3	5.7	0.7	1.9	0.3	0.9
Children							
Belgium (Regional Flanders)	625	2.2	4.8	0.7	1.7	0.4	1.1
Bulgaria (NUTRICHILD)	433	0.6	1.5	0.3	0.9	0.2	0.6
Czech Republic (SISP04)	389	0.9	2.2	0.4	1.2	0.2	0.7
Germany (DONALD 2006 2008)	660	0.9	2.2	0.4	1.2	0.2	0.7
Denmark (Danish Dietary Survey)	490	0.7	1.5	0.4	0.9	0.2	0.5
Spain (enKid)	156	0.9	2.4	0.3	0.9	0.1	0.4
Spain (NUT INK05)	399	0.8	2.1	0.2	0.7	0.1	0.3
Finland (DIPP 2003 2006)	933	0.8	2.0	0.2	0.6	0.1	0.3
Finland (STRIP)	250	0.9	1.9	0.4	0.9	0.2	0.5
France (INCA2)	482	0.9	1.9	0.3	0.9	0.1	0.4
Greece (Regional Crete)	839	0.6	1.3	0.2	0.6	0.1	0.3
Italy (INRAN SCAI 2005 06)	193	0.5	1.1	0.1	0.3	0.1	0.2
Latvia (EFSA TEST)	189	0.6	1.5	0.3	0.8	0.2	0.4
Netherlands (VCP kids)	957	2.0	4.7	0.6	1.5	0.3	0.8
Sweden (NFA)	1 473	1.4	2.8	0.6	1.3	0.4	0.8
Adolescents							
Belgium (Diet National 2004)	584	0.6	1.3	0.4	1.0	0.2	0.6
Cyprus (Childhealth)	303	0.2	0.4	0.1	0.3	0.0	0.2
Czech Republic (SISP04)	298	0.6	1.6	0.3	0.9	0.2	0.5
Germany (National Nutrition Survey II)	1 011	0.4	1.1	0.2	0.8	0.1	0.4
Denmark (Danish Dietary Survey)	479	0.5	1.2	0.3	0.8	0.2	0.5
Spain (AESAN FIAB)	86	0.3	0.7	0.1	0.5	0.1	0.2
Spain (enKid)	209	0.4	1.1	0.2	0.6	0.1	0.3
Spain (NUT INK05)	651	0.4	1.0	0.2	0.6	0.1	0.3
France (INCA2)	973	0.4	1.0	0.2	0.5	0.1	0.3
Italy (INRAN SCAI 2005 06)	247	0.3	0.8	0.1	0.3	0.1	0.2
Latvia (EFSA TEST)	470	0.4	1.0	0.2	0.6	0.1	0.3
Sweden (NFA)	1 018	0.8	1.7	0.4	0.9	0.2	0.5



	Number of	MPLs scenario		Brand-loyal scenario		Non-brand-loyal scenario	
	subjects	Mean	High level	Mean	High level	Mean	High level
Adults							
Belgium (Diet National 2004)	1 304	0.5	1.2	0.3	0.8	0.1	0.5
Czech Republic (SISP04)	1 666	0.3	0.8	0.1	0.5	0.1	0.2
Germany (National Nutrition Survey II)	10 419	0.3	0.8	0.1	0.5	0.1	0.3
Denmark (Danish Dietary Survey)	2 822	0.2	0.7	0.1	0.5	0.1	0.3
Spain (AESAN)	410	0.3	0.7	0.1	0.4	0.1	0.2
Spain (AESAN FIAB)	981	0.2	0.6	0.1	0.3	0.0	0.2
Finland (FINDIET 2007)	1 575	0.2	0.7	0.1	0.3	0.0	0.1
France (INCA2)	2 276	0.2	0.6	0.1	0.3	0.0	0.2
United Kingdom (NDNS)	1 724	0.2	0.6	0.1	0.4	0.1	0.2
Hungary (National Repr Surv)	1 074	0.2	0.5	0.1	0.4	0.1	0.2
Ireland (NSIFCS)	958	0.2	0.6	0.1	0.4	0.1	0.2
Italy (INRAN SCAI 2005 06)	2 313	0.2	0.5	0.0	0.2	0.0	0.1
Latvia (EFSA TEST)	1 306	0.2	0.6	0.1	0.3	0.0	0.1
Netherlands (DNFCS 2003)	750	0.6	1.4	0.3	0.9	0.2	0.5
Sweden (Riksmaten 1997 98)	1 210	0.3	0.7	0.1	0.4	0.1	0.3
The elderly							
Belgium (Diet National 2004)	1 230	0.3	0.8	0.1	0.4	0.1	0.2
Germany (National Nutrition Survey II)	2 496	0.2	0.6	0.1	0.2	0.0	0.1
Denmark (Danish Dietary Survey)	329	0.1	0.4	0.1	0.2	0.0	0.1
Finland (FINDIET 2007)	463	0.1	0.4	0.0	0.1	0.0	0.0
France (INCA2)	348	0.2	0.4	0.1	0.2	0.0	0.0
Hungary (National Repr Surv)	286	0.1	0.4	0.1	0.2	0.0	0.1
Italy (INRAN SCAI 2005 06)	518	0.1	0.4	0.0	0.1	0.0	0.0

(a): The 95th percentile estimates obtained on dietary surveys/population groups with fewer than 60 observations may not be statistically robust (EFSA, 2011a). Those estimates were not included in this table.



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	FoodDrinkEurope					
ICGA	International Chewing Gum Association					
JECFA	Joint FAO/WHO Expert Committee on Food Additives					
LOD	limit of detection					
LOQ	limit of quantification					
MB	medium 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					