

STATEMENT OF EFSA

Refined exposure assessment for curcumin (E 100)¹

European Food Safety Authority^{2, 3}

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ABSTRACT

Following a self-tasking request, the European Food Safety Authority (EFSA) carried out a refined exposure assessment for curcumin (E 100) taking into account additional information on its use in foods. In 2010, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) adopted a scientific opinion on the re-evaluation of curcumin (E 100) used as a food additive. In that opinion, the Panel concluded that at the maximum levels of use, intake estimates for 1 to 10-year old children at the mean and the high level can be above the Acceptable Daily Intake (ADI) of 3 mg/kg body weight per day in some European countries. Following this conclusion, EFSA performed a refined exposure assessment for this food colour, using new usage data from industry, as well as monitoring data from Member States submitted to EFSA and the EFSA Comprehensive European Food Consumption Database. Usage data from industry were provided to EFSA for 52 out of the 57 food categories in which curcumin is authorised as a food additive. Analytical results provided to EFSA from Member States were all below the limit of detection (LOD) except for four samples of the food category edible ices. Using the reported use levels, exposure estimates for adolescents, adults and the elderly were below the ADI both at the mean and at the high level (95th percentile) of exposure. This was also true for the mean exposure estimates for toddlers and children. High level estimates were at the level of the ADI in these two population groups, with exceedance of the ADI in one survey each. In comparison to the previous assessment of 2010, the current exposure estimates based on reported use levels and consumption data at individual level were lower.

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KEY WORDS

curcumin, E 100, 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) of a scientific opinion on the re-evaluation of curcumin (E 100) used as a food additive in 2010, in which the Panel concluded that at the maximum levels of use, intake estimates for 1- to 10-year old children at the mean and at the high level could be above the Acceptable Daily Intake (ADI), EFSA carried out a refined exposure assessment for this colour, taking into account additional information on its use and use levels in foods.

Curcumin (E 100) is a cinnamoylmethane dye authorised as a food additive in the EU. This food colour has been previously evaluated by the Scientific Committee for Food (SCF) in 1975 and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1974, 1978, 1980, 1982, 1987, 1990, 1992, 1995, 2000, 2002 and 2004.

In 2010, the ANS Panel re-evaluated curcumin (E 100) as a food additive (EFSA, 2010a). The safety in use of curcumin (E 100) 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 established for curcumin an acceptable daily intake (ADI) of 3 mg/kg body weight (bw)/day based on the No-Observed-Adverse-Effect Level (NOAEL) of a reproductive toxicity study.

The ANS Panel concluded that at the maximum levels of use of curcumin (E 100), intake estimates for 1- to 10-year old children, both at the mean and the high percentiles (95th or 97.5th) were above the ADI in some European countries.

The present review provides a refined exposure assessment for curcumin (E 100) based on individual food consumption data which became available within the EFSA Comprehensive European Food Consumption Database and newly submitted information on the actual use levels and concentration data of curcumin (E 100) in foods as consumed, provided to EFSA by the food industry and Member States, following an EFSA call for data⁵ launched in March 2013.

Use levels of curcumin (E 100) reported by industry cover the majority of the authorised uses of curcumin as a food additive.

EFSA concluded that following the regulatory maximum level exposure assessment scenario, exposure estimates for toddlers, children and adolescents population groups were similar to those reported in the previous opinion of the ANS Panel in 2010 (EFSA, 2010a): both at mean and high level (95th percentile) exposure the ADI was exceeded; while adults and the elderly exposure estimates are below the ADI.

In the refined exposure assessment scenarios, using information on use levels and the EFSA Comprehensive Database, exposure estimates for adults and the elderly were lower than those reported in the previous opinion (EFSA, 2010a). The current exposure estimates for these population groups, as well as for adolescents, were below the ADI, both at the mean and at the high level (95th percentile). For children and toddlers, current exposure estimates were also lower compared to the previous opinion, both at the mean and at the high level. However, high level estimates were at the level of the ADI in these two population groups, with exceedance of the ADI in one survey each.

Intake of curcumin from natural sources was minor compared to the total intake of curcumin and did not affect the overall result with regards to the exceedance of the ADI in 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. <http://www.efsa.europa.eu/en/data/call/130327.htm>

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BACKGROUND AS PROVIDED BY EFSA

In its letter of 26 May 2011 to the European Food Safety Authority (EFSA), the European Commission requested clarification on the outcomes of the exposure calculations undertaken by the ANS Panel in the opinions on the so-called Southampton colours (quinoline yellow⁶, sunset yellow⁷, ponceau 4R⁸). 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 Commission, and Member States representatives, where the possibility to make refined exposure assessments in the future was discussed, further exchanges between the Commission 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 of the EFSA Comprehensive Food Consumption Database (FoodEx) had been finalised, in its letter of 26 April 2012, EFSA has requested information on the priorities set by the Commission.

On 23 May 2012, the European Commission sent a letter to EFSA setting the priorities for the refined exposure assessments of twelve 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), ponceau 4R (E 124)) and indicating 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 Commission to EFSA.

TERMS OF REFERENCE AS PROVIDED BY 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 food classification system of Regulation (EU) No 1129/2011 and of the EFSA Comprehensive Food Consumption Database (FoodEx), EFSA will use the FoodEx 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 European Commission, 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.

ASSESSMENT

1. Introduction

Curcumin (E 100) is a cinnamoylmethane dye authorised as a food additive in the EU. This food colour has previously been evaluated by the Scientific Committee for Food (SCF) in 1975 and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1974, 1978, 1980, 1982, 1987, 1990, 1992, 1995, 2000, 2002 and 2004.

In 2010, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) re-evaluated curcumin (E 100) as a food additive (EFSA, 2010a). The safety of the use of curcumin (E 100) was assessed on the basis of uses and use levels authorised in the legislation¹⁰ and of reported use levels, as provided by industry. The ANS Panel established for curcumin an Acceptable Daily Intake (ADI) of 3 mg/kg body weight (bw)/day based on the No-Observed-Adverse-Effect Level (NOAEL) of a reproductive toxicity study.

The ANS Panel concluded that at the maximum levels of use of curcumin (E 100), intake estimates for 1- to 10-year old children, both at the mean and the high percentiles (95th or 97.5th), were above the ADI in some European countries. The main contributors to the total anticipated mean exposure of adult population to curcumin (E 100) were non-alcoholic beverages (50 %). For children, the main contributing food categories were fine bakery wares (e.g. viennoiserie, biscuits, cakes, wafer) (13-47 %), desserts (including flavoured milk products) (13-52 %), non-alcoholic beverages (15-57 %) and sauces and seasonings (11-45 %). Confectionery accounted for 14 % in one country in children.

The aim of the present assessment is to provide a refined exposure assessment for curcumin (E 100) from its use as a food colour following the approach agreed by the ANS Panel at its 52nd plenary meeting¹¹ to be followed for the refined exposure assessment as part of the safety assessment of food additives under re-evaluation (Section 4.1). The current exposure assessment therefore uses the EFSA Comprehensive European Food Consumption Database and the FoodEx classification system and takes into consideration, besides the maximum permitted levels (MPLs), updated use levels reported by industry and analytical data from national monitoring programmes, when available. In March 2013, EFSA launched a call¹² for analytical data and use levels for curcumin (E 100) and new data were received from industry and Member States (Appendices A and B).

1.1. Previously reported exposure assessment of curcumin (E 100)

Table 1 presents the dietary exposure to curcumin (E 100) as estimated by the ANS Panel in 2010 for two population groups: children and adults (EFSA, 2010a).

¹⁰ 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.

¹¹ <http://www.efsa.europa.eu/en/events/event/140701a-m.pdf>

¹² 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>

Table 1: Summary of anticipated exposure to curcumin (E 100) in children and the adult population as reported in the previous ANS Panel opinion (EFSA, 2010a) (mg/kg bw/day)

	UK Adults ^(a) (>18 years old)	UK ^(a) & EXPOCHI ^(b) Children (1-10 years old, 15.8-29 kg body weight)
Estimated exposure using MPLs		
• Mean exposure	0.9	0.5 – 3.8
• Exposure 95 th or 97.5 th percentile	3.3	1.2 – 7.2
Estimated exposure using reported use levels		
• Mean exposure	0.8	0.5 – 3.4
• Exposure 95 th or 97.5 th percentile	2.0	1.1 – 7.1

(a); For UK, estimates are based on the Union of European Soft Drinks Associations (UNESDA) 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 report, which gives the 95th percentile intake.

2. Use and use levels of curcumin (E 100)

2.1. Maximum Permitted Levels of use

Maximum Permitted Levels (MPLs) of curcumin (E 100) have been defined in Annex II to Regulation (EC) No 1333/2008¹³ on food additives.

Currently, curcumin (E 100) is an authorised food colour in the EU with MPLs ranging from 50 to 500 mg/kg in foods and at *quantum satis* (QS) in some food categories. In addition, curcumin (E 100) is included in Group III of food colours with combined maximum limits 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 curcumin (E 100) and the corresponding MPLs as set by Annex II to Regulation (EC) No 1333/2008.

Table 2: Food categories in which curcumin (E 100) is authorised to be used as a food additive according to Annex II of Regulation (EC) No 1333/2008

FCS* Category No	Food categories	E number/ group	Maximum permitted level (mg/l or mg/kg as appropriate)	Restrictions/exceptions
1.4	Flavoured fermented milk products including heat-treated products	Group III	150	
1.6.3	Other creams	Group III	150	only flavoured creams
1.7.1	Unripened cheese excluding products falling in category 16	Group III	150	only flavoured unripened cheese
1.7.3	Edible cheese rind	Group III	<i>quantum satis</i>	
1.7.5	Processed cheese	E 100	100 ^(a)	only flavoured processed cheese
1.7.6	Cheese products (excluding products falling in category 16)	Group III	100	only flavoured unripened products

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

FCS* Category No	Food categories	E number/ group	Maximum permitted level (mg/l or mg/kg as appropriate)	Restrictions/exceptions
2.1	Fats and oils essentially free from water (excluding anhydrous milkfat)	E 100	<i>quantum satis</i>	only fats
2.2.2	Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions	E 100	<i>quantum satis</i>	excluding reduced fat butter
3	Edible ices	Group III	150	
4.2.4.1	Fruit and vegetable preparations excluding compote	Group III	200	only <i>mostarda di frutta</i>
4.2.4.1	Fruit and vegetable preparations excluding compote	E 100	50	only seaweed based fish roe analogues
4.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EEC	E 100	<i>quantum satis</i>	except chestnut puree
4.2.5.3	Other similar fruit or vegetable spreads	E 100	<i>quantum satis</i>	except <i>crème de pruneaux</i>
4.2.6	Processed potato products	E 100	<i>quantum satis</i>	only dried potato granules and flakes
5.2	Other confectionery including breath freshening microsweets	Group III	300	except candied fruit and vegetables
5.2	Other confectionery including breath freshening microsweets	Group III	200	only candied fruit and vegetables
5.3	Chewing gum	Group III	300	
5.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	Group III	500	only decorations, coatings and sauces, except fillings
5.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	Group III	300	only fillings
6.6	Batters	Group III	500	only batters for coating
7.2	Fine bakery wares	Group III	200	
8.2.1	Non heat-treated processed meat	E 100	20	only sausages
8.2.1	Non heat-treated processed meat	E 100	<i>quantum satis</i>	only <i>pasturmas</i>
8.2.2	Heat-treated processed meat	E 100	20	only sausages, patés and terrines
8.2.3	Casings and coatings and decorations for meat	Group III	500	only decorations and coatings except edible external coating of <i>pasturmas</i>
8.2.3	Casings and coatings and decorations for meat	Group III	<i>quantum satis</i>	only edible casings
8.2.3	Casings and coatings and decorations for meat	E 100	<i>quantum satis</i>	only edible external coating of <i>pasturmas</i>
9.2.	Processed fish and fishery products including mollusks and crustaceans	Group III	500	only surimi and similar products and salmon substitutes
9.2.	Processed fish and fishery products including mollusks and crustaceans	E 100	100 ^(b)	only fish paste and crustacean paste

FCS* Category No	Food categories	E number/ group	Maximum permitted level (mg/l or mg/kg as appropriate)	Restrictions/exceptions
9.2.	Processed fish and fishery products including mollusks and crustaceans	E 100	250 ^(c)	only precooked crustacean
9.2.	Processed fish and fishery products including mollusks and crustaceans	E 100	100 ^(d)	only smoked fish
9.3	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	
12.6	Sauces	Group III	500	including pickles, relishes, chutney and picalilli; 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 <i>cidre bouché</i>
14.2.4	Fruit wine and made wine	Group III	200	Excluding <i>wino owocowe markowe</i>
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 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
14.2.7.1	Aromatised wines	Group III	200	except <i>americano</i> , <i>bitter vino</i>
14.2.7.1	Aromatised wines	E 100	100 ^{(e) (f)}	only <i>americano</i> , <i>bitter vino</i>
14.2.7.2	Aromatised wine-based drinks	Group III	200	except <i>bitter soda</i> , <i>sangria</i> , <i>claria</i> , <i>zurra</i>
14.2.7.2	Aromatised wine-based drinks	E 100	100 ^(g)	only <i>bitter soda</i>
14.2.7.3	Aromatised wine-product cocktails	Group III	200	

FCS* Category No	Food categories	E number/ group	Maximum permitted level (mg/l or mg/kg as appropriate)	Restrictions/exceptions
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 <i>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</i> and <i>aromatyzowane wino owocowe niskoalkoholowe</i>
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 category 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

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

(a): Maximum individually or for the combination of E 100, E 102, E 120, E 122, E 160e and E 161b.

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

(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): Maximum individually or for the combination of E 100, E 102, E 120, E 151, E 160e.

(e): In *americano* E 100, E 101, E 102, E 104, E 120, E 122, E 100, E 124 are authorised individually or in combination.

(f): In *bitter vino* E 100, E 101, E 102, E 104, E 110, E 120, E 122, E 100, E 124, E 129 are authorised individually or in combination.

(g): In *bitter soda* E 100, E 101, E 102, E 104, E 110, E 120, E 122, E 100, E 124, E 129 are authorised individually or in combination.

2.2. Reported use levels or data on analytical levels of curcumin (E 100) 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 for performing a

more realistic exposure assessment, especially for the food categories where no MPL is set and when the food additive is authorised according to *QS*.

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 call¹⁴ for concentration data (usage and analytical data) on curcumin (E 100) in March 2013 with deadline mid-September 2013.

Data on curcumin (E 100) including present use and use patterns (i.e. the food categories and subcategories, proportion of food within categories/subcategories in which it is used, actual use levels (typical and maximum use levels), especially for those uses which are only limited by *QS*) were requested from relevant stakeholders. European food manufacturers, national food authorities, research institutions, academia, food business operators and any other interested stakeholders were invited to submit analytical data on curcumin (E 100) in foods. The data submission to EFSA followed the requirements of the EFSA Guidance on Standard Sample Description for Food and Feed (EFSA, 2010b).

In response to this public call, updated information on the actual use levels of curcumin (E 100) in foods was made available to EFSA by industry and Member States.

2.2.1. Summarised data on reported use levels of curcumin in foods provided by industry

Industry provided EFSA with data on use levels (n=237) of curcumin (E 100) in foods for 52 out of the 57 food categories in which curcumin is authorised. Updated information on the actual use levels of curcumin (E 100) in foods was made available to EFSA by Food Drink Europe (FDE), Natural Food Colours Association (NATCOL), the International Chewing Gum Association (ICGA) and one private company. For the food categories edible cheese rind (FCS 01.7.3), fats and oils essentially free from water (FCS 02.1), fruit and vegetable preparations excluding compote, only seaweed based fish roe analogues (FCS 04.2.4.1), batters (FCS 06.6), non heat-treated processed meat, only *pasturmas* (FCS 08.2.1) and casings and coatings and decorations for meat, only edible external coating of *pasturmas* no reported use levels were provided.

It should be noted that in May 2013, and while the EFSA call for use level and/or concentration data was ongoing, the Annex II to Regulation No 1333/2008 was amended in relation to some MPLs of use for curcumin (Commission Regulation (EU) No 438/2013¹⁵). In particular, MPLs of curcumin in food category Processed fish and fishery products including molluscs and crustaceans (FCS 09.2), with the two exceptions of 'only fish paste and crustacean paste' and 'only smoked fish' changed from *QS* to a MPL of 100 mg/kg. It is noteworthy that the industry reported levels above the MPLs of 100 mg/kg for both sub-categories, i.e. 300 mg/kg and 200 mg/kg, respectively. For the present exposure assessment, values above the current MPLs, as amended by Regulation (EU) No 438/2013, were not taken into account. MPLs were used instead.

Several values were reported by industry (minimum, typical and maximum levels of use) for the same food category. 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. Maximum levels reported on some products defined as 'niche products' (NP) by the industry (e.g. with very limited representativeness on the EU market) within a food category were not taken into account in the exposure assessment. In those cases, typical and maximum levels were based on the remainder of the foods belonging to the same food category, except when no other data were made available to EFSA for that food category.

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

¹⁵ Commission Regulation (EU) No 438/2013 of 13 May 2013 amending and correcting Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of certain food additives. OJ L 129, 14.5.2013, p. 28.

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

2.2.1.1. Summarised data on analytical results of curcumin 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, 291 analytical results were reported to EFSA by two countries: Germany (n=281) and Hungary (n=10). Only 10 of these samples came from a non-accredited laboratory. The data were mainly on flavoured drinks (FCS 14.1.4). Foods were sampled between 2007 and 2013 and analysed the same year of collection. Curcumin (E 100) was not detected (< limit of detection (LOD)) in 287 samples. In four out of the 291 samples, quantified levels of curcumin were reported.

Information was received on 13 food categories, in nine of which the use of curcumin as a food additive is not authorised. Out of the 291 analytical results, 265 were on the four remaining food categories: fermented milk products (FCS 01.4), edible ices (FCS 03), seasonings and condiments (FCS 12.2.2) and flavoured drinks (FCS 14.1.4). The samples with quantified levels (at or above LOQ) were all related to edible ices (FCS 03) with maximum of 14.6 mg/kg, which were below the use level reported by industry.

Considering that the number of analytical results obtained from the public call for data was low, and that they were all below the use levels reported by industry, only the reported use levels were used in the assessment.

Appendix B shows the analytical results of curcumin (E 100) in foods as reported by Member States.

3. Food consumption

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 from the European countries provide EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. 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 due to possible subjects' 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 classification system (EFSA, 2011b). Nomenclature from the FoodEx classification system has been linked to the Food Categorisation System (FCS), as presented in Annex II to Regulation (EC) No 1333/2008, as amended for the exposure assessment.

3.2. Food items selected for the refined exposure assessment of curcumin (E 100)

The food categories in which the use of curcumin (E 100) 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 results in an underestimation of the exposure. The food

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

- 01.7.3. Edible cheese rind
- 01.7.6. Cheese products (excluding products falling in category 16), only flavoured unripened products
- 04.2.4.1. Fruit and vegetable preparations excluding compote, only *mostarda di frutta* and only seaweed based fish roe analogues
- 05.4. Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4, only decorations, coatings and sauces, except fillings and only fillings
- 06.6. Batters
- 08.2.3. Casings and coatings and decorations for meat
- 14.2.4. Fruit wine and made wine

The food category other creams (FCS 01.6.3) could not be distinguished from the food category cream and cream powder (FCS 01.6); the restriction on flavoured creams could neither be distinguished from plain cream. The food category 'other cream – only flavoured creams' (FCS 01.6.3) was therefore also not taken into account in the present estimate.

For the following food categories, referenced in the EFSA Comprehensive Database, the restrictions which apply to the use of curcumin could not be taken into account in the exposure assessment, and therefore the whole food category was considered for the exposure estimates. This results in an overestimation of the exposure:

- For the food categories: 01.7.1, 01.7.5 and 01.7.6, distinction between flavoured and non-flavoured foods is not possible within the EFSA Comprehensive Database.
- For the following food categories it is not possible to make a distinction of the foods defined under the restrictions applicable to the use of curcumin: FCS 02.2.2 excluding reduced fat butter, FCS 04.2.5.2 excluding chestnut purée and FCS 04.2.5.3 excluding *crème de pruneaux*.
- 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* 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 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.

For the food category fats and oils essentially free from water (FCS 02.1), no reported use or analytical levels were made available to EFSA and therefore this food category was not considered in the exposure assessment. EFSA noted that if curcumin (E 100) is nevertheless used in this food category, the calculated refined exposure assessment might result in underestimation of exposure to curcumin.

Overall, one food category was not included in the exposure assessment because no data was made available to EFSA, eight food categories were not taken into account in the exposure assessment because they are not referenced in the EFSA Comprehensive Database and 11 food categories were included in the exposure assessment without considering the restrictions as set in Annex II to Regulation No 1333/2008. These sources of uncertainties will be described in section 6.

4. Dietary exposure assessment

Dietary exposure to curcumin (E 100) from its use as a food colour was estimated based on the consumption data available within the EFSA Comprehensive Database as presented in Section 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 mentioned in Table 3. Calculations were performed using individual body weights. For calculation of chronic exposure, intake statistics were calculated based on individual average consumption over the total survey period excluding surveys with only one day per subject. These surveys were excluded because one day per subject was considered by the EFSA Working Group on Food Consumption and Exposure (EFSA, 2011a) as not adequate to assess repeated dietary exposure. High percentile exposure was only calculated 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 were not included.

Table 3: Population groups considered for the exposure estimates of curcumin (E 100)

Population	Age range	Countries with food consumption surveys covering more than one day
Toddlers	from 12 up to and including 35 months of age	Belgium, Bulgaria, Finland, Germany, Italy, Netherlands, Spain
Children ¹⁶	from 36 months up to and including 9 years of age	Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Spain, Sweden
Adolescents	from 10 up to and including 17 years of age	Belgium, Cyprus, Czech Republic, Denmark, France, Germany, Italy, Latvia, Spain, Sweden
Adults	from 18 up to and including 64 years of age	Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Spain, Sweden, UK
The elderly ¹⁶	from 65 years of age and older	Belgium, Denmark, Finland, France, Germany, Hungary, Italy

¹⁶ The terms “children” and “the elderly” correspond respectively to “other children” and the merge 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 Food Classification System (FCS) as presented in the 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 and values reported in Appendix C for each food category with their respective consumption amount per kg bw 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, 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 (Table 3).

4.1. Exposure to curcumin (E 100) from its use as a food additive

Exposure assessment to curcumin 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 adequate use levels or analytical data (defined as the *refined exposure assessment* scenario).

4.1.1.1. 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 most conservative since in this scenario it is assumed that consumers will be continuously (over a lifetime) exposed to curcumin present in the authorised food categories at MPLs.

4.1.1.2. Refined exposure assessment scenario

The refined exposure assessment scenario was based on information on reported use levels by industry. This exposure scenario only considers food categories for which use levels were made available to EFSA.

Appendix C summarises the concentration levels of curcumin used in the refined exposure assessment scenario. Based on the available dataset, EFSA calculated two estimates based on different model populations:

- (1) The brand-loyal consumer scenario: It was assumed that a consumer is exposed long-term to the food additive present at the maximum reported use level for one food category. This exposure estimate was calculated as follows:
 - Combining food consumption with the maximum of the maximum reported use levels for the main contributing food category at the individual level.
 - Using the mean of the typical reported use levels for the remaining food categories per individual.
- (2) The non-brand-loyal consumer scenario: It was assumed that the population is exposed long-term to the food additive present at the mean reported use levels per food category. This exposure estimate was calculated using the mean of the typical reported use levels for all food categories.

Table 4 summarises the anticipated exposure to curcumin (E 100) from its use as a food additive for all five population groups (Table 3). Detailed results by population group and survey are presented in Appendix D.

Table 4: Summary of anticipated exposure to curcumin (E 100) from its use as a food additive using the regulatory maximum level exposure assessment scenario and the refined exposure scenarios in five population groups (min-max across the dietary surveys in mg/kg bw/day)

	Toddlers (12-35 months)	Children (3-9 years)	Adolescents (10-17 years)	Adults (18-64 years)	The elderly (>65 years)
Regulatory maximum level exposure assessment scenario					
• Mean	0.9-3.9	0.9-3.2	0.3-1.6	0.3-1.1	0.1-0.6
• High level	2.8-7.2	2.0-6.7	1.0-3.3	0.7-2.3	0.5-1.4
Refined estimated exposure scenario					
Brand-loyal scenario					
• Mean	0.4-2.0	0.6-1.6	0.2-0.9	0.2-0.6	0.1-0.4
• High level	1.4-3.3	1.2-3.4	0.7-2.3	0.4-1.5	0.3-0.9
Non-brand-loyal scenario					
• Mean	0.1-0.8	0.2-0.6	0.1-0.3	0.1-0.2	0.03-0.2
• High level	0.5-1.2	0.5-1.2	0.2-0.7	0.2-0.5	0.1-0.4

4.2. Main food categories contributing to exposure to curcumin (E 100)

The main food categories contributing to total mean exposure to curcumin (E 100) (> 5 % of total exposure) calculated using the regulatory maximum level exposure scenario and using the refined exposure assessment scenarios, as well as the number of surveys in which each food category was a main contributor are shown in Tables 5, 6 and 7, respectively.

Table 5: Main food categories contributing to the total mean exposure to curcumin (E 100) using the regulatory maximum level exposure scenario (> 5 % of total exposure) and number of surveys in which each food category is contributing

FCS Category number	Foods	Toddlers	Children	Adolescents	Adults	The elderly
		Range of % contribution to the total exposure (Number of surveys) ^(a)				
01.4	Flavoured fermented milk products including heat-treated products	6.5-73.8 (7)	7.4-36.3 (13)	6-14.5 (9)	5.3-32.9 (12)	6.5-30.9 (6)
01.7.1	Unripened cheese excluding products falling in category 16	5.5-7.8 (3)	5.6-16.8 (3)	20.3 (1)	5.6-26.6 (5)	5.5-25.5 (5)
01.7.5	Processed cheese	8.6-11 (2)				
03	Edible ices	5.1-14.7 (2)	5.6-12.8 (9)	5.2-11.8 (4)	7-8.6 (3)	6.5 (1)
05.2	Other confectionery including breath freshening microsweets		5-10.3 (5)	7.3-10 (2)	8.7-9.4 (2)	5.3-5.8 (2)
07.2	Fine bakery wares	11.3-54.3 (6)	11.9-47.8 (13)	13.5-42.9 (11)	5.4-41.4 (14)	10.8-34.1 (6)
08.2	Processed meat				5.4 (1)	
09.2	Processed fish and fishery products including molluscs and crustaceans		6.1 (1)	5.9-5.9 (2)	6-6.6 (3)	
12.5	Soups and broths	6.5 (1)	5.1-14.7 (3)	13.3 (1)	7.5-18.1 (2)	7.6-16.7 (2)
12.6	Sauces	6.1-12.1 (4)	5.8-25.7 (12)	7.5-35 (10)	7.4-33.6 (14)	5.4-27.2 (6)
14.1.4	Flavoured drinks	5-27.7 (5)	8.7-48.6 (14)	5.9-61.7 (12)	6.3-51.4 (14)	6.5-44.2 (4)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts				8.1-17.9 (4)	5.7-12.8 (3)
15.1	Potato-, cereal-, flour- or starch-based snacks	7.4 (1)		8.8-10.5 (2)		
16	Desserts excluding products covered in category 1, 3 and 4	11.9-13.1 (2)	5-10 (5)	8 (1)	5.3-5.9 (2)	7.2 (1)

(a): The total number of surveys may be greater than the total number of countries as 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 curcumin (E 100) using the brand-loyal refined exposure scenario, (> 5 % of total exposure) and number of surveys in which each food category is contributing

FCS Category number	Foods	Toddlers	Children	Adolescents	Adults	The elderly
		Range of % contribution to the total exposure (Number of surveys) ^(a)				
01.4	Flavoured fermented milk products including heat-treated products	12.7-69.6 (6)	5.9-27.1 (8)	5.7-6.1 (2)	5.1-21.9 (2)	9.3-21.5 (2)
01.7.1	Unripened cheese excluding products falling in category 16	5.7-6.9 (4)	5.5-13.7 (3)	18.2 (1)	6.7-29 (2)	5.2-28.5 (4)
01.7.5	Processed cheese	8.4-21.8 (2)				
03	Edible ices	14.2 (1)	5.1-10.5 (5)	9.6 (1)	5.3-6.3 (2)	
04.2	Processed fruit and vegetables	6.8 (1)				
05.2	Other confectionery including breath freshening microsweets		6.8-13 (2)	5.8-5.9 (2)	7.2-11.2 (2)	6.1-6.3 (2)
07.2	Fine bakery wares	8.5-66 (6)	11.8-68.2 (13)	12.9-59.8 (11)	11.3-54.6 (13)	11.9-43.7 (6)
08.2	Processed meat				6.1 (1)	
09.2	Processed fish and fishery products including molluscs and crustaceans		6.8 (1)	6.8 (1)	5.1-7.5 (3)	
12.5	Soups and broths	6.3 (1)	5.2-12.9 (3)	12.8 (1)	7.3-17.4 (2)	7.2-18.4 (2)
12.6	Sauces	10.1-13.9 (3)	8.5-37.6 (11)	5.8-43.1 (9)	6.3-46 (14)	6-33.4 (6)
14.1.4	Flavoured drinks	9.4-43.1 (5)	6.7-71.5 (14)	5.8-82.1 (12)	5.3-70.2 (15)	10.7-51.8 (4)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts				7.2-14.6 (4)	7.8-12.3 (2)
15.1	Potato-, cereal-, flour- or starch-based snacks	5.3-8.7 (2)		8.2-10.2 (2)		

(a): The total number of surveys may be greater than the total number of countries as 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 curcumin (E 100) using the non brand-loyal refined exposure scenario, (> 5 % of total exposure) and number of surveys in which each food category is contributing

FCS Category number	Foods	Toddlers	Children	Adolescents	Adults	The elderly
		Range of % contribution to the total exposure (Number of surveys) ^(a)				
01.4	Flavoured fermented milk products including heat-treated products	14.5-59.7 (6)	6-23 (11)	5.5-8.8 (4)	5.3-20.1 (5)	5.5-17.8 (3)
01.7.1	Unripened cheese excluding products falling in category 16	5.6-7.1 (4)	8.6-14.3 (2)	17.6 (1)	5.2-23.6 (4)	5.3-22 (4)
01.7.5	Processed cheese	8.9-13.5 (2)	-	-	-	-
03	Edible ices	12.4 (1)	5.1-11.5 (8)	9.2 (1)	5.2-6.9 (3)	5 (1)
04.2	Processed fruit and vegetables	8.8 (1)	-	-	-	5.1-5.8 (3)
05.2	Other confectionery including breath freshening microsweets	5.7 (1)	6.5-14 (6)	9.3-14.3 (2)	11.3-12.7 (2)	6.4-7.3 (2)
07.2	Fine bakery wares	14.9-58.9 (6)	5.2-54.2 (14)	16.7-45.8 (11)	7.2-44.6 (14)	13.3-38.3 (6)
08.2	Processed meat	7.3 (1)	5.3-7.8 (3)	5.8-6.2 (2)	5.4-18.2 (5)	8.2-15.4 (3)
09.2	Processed fish and fishery products including molluscs and crustaceans	-	8.7 (1)	5-7.1 (2)	5.5-6.8 (3)	-
12.5	Soups and broths	5-13.9 (2)	5.2-23.6 (5)	5.3-21 (4)	7.5-27.1 (4)	12.3-26.7 (2)
12.6	Sauces	5.9-16.1 (5)	7.6-29.8 (12)	8.5-38.1 (10)	8.6-37.4 (14)	6.2-27.5 (6)
14.1.4	Flavoured drinks	10.7-21.1 (4)	5.6-37.1 (14)	5.3-49.5 (11)	5.6-39.1 (13)	5.8-29 (3)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	-	-	-	6.2-17.4 (4)	9.2-13 (2)
15.1	Potato-, cereal-, flour- or starch-based snacks	9.3-11.1 (2)	5.3-7.6 (5)	5.1-16.8 (5)	5-6.5 (4)	-
16	Desserts excluding products covered in category 1, 3 and 4	7.8-8.4 (2)	5.4-6.2 (2)	-	-	-

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

5. Discussion

EFSA has performed a refined exposure assessment for curcumin (E 100) 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 adequate data on its actual uses from the newly submitted data by industry.

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 when performing a refined dietary exposure assessment to food additives. However, given the extensive range of concentration data that have been made available through the most recent calls for data, EFSA considered that exposure scenarios should be revised to include all data submitted to provide more realistic exposure estimates.

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

Overall, exposure estimates of the regulatory maximum level exposure assessment scenario should be considered as the most conservative since this scenario assumes that the consumer will continuously (over a lifetime) be exposed to curcumin present in the food at MPLs. The refined exposure assessment approach is considered as a more realistic scenario. It is based on the extensive range of use data and assumes either that all food categories contain the additive at the mean use level (non-brand-loyal consumer scenario) or that one food category contains curcumin at the maximum use level provided and the rest at the mean level (brand-loyal consumer scenario). For both refined scenarios, food categories for which no use levels were available were not considered in the exposure assessment. Therefore, it should be noted that if curcumin is nevertheless used in those food categories, the calculated refined exposure assessment might have resulted in an underestimation of exposure to curcumin. EFSA also noted that the refined exposure estimates does not cover future changes in the level of use of curcumin.

Using the regulatory maximum level exposure assessment scenario, exposure estimates for adults and the elderly were below the ADI of 3 mg/kg bw/day established for curcumin, both at the mean and at the high level of exposure (95th percentile). For adolescents, exposure estimates were below the ADI at the mean but exceeded the ADI at the high level. Exposure estimates of toddlers and children exceeded the ADI both at the mean and at the high level. The main contributing food categories to the total mean exposure estimates for adolescents, adults and the elderly were flavoured drinks and fine bakery wares. For children, the main contributing food categories were flavoured drinks, fine bakery wares and flavoured fermented milk products, while for toddlers, the main contributing food categories were flavoured fermented milk products and fine bakery wares.

For the refined brand-loyal assessment exposure scenario, exposure estimates for all population groups were below the ADI at the mean, but exceeded the ADI at the high level (95th percentile) for toddlers and children (in one survey for each population group). The main contributing food categories to the total mean exposure estimates for children, adolescents, adults and the elderly were flavoured drinks and fine bakery wares. For toddlers, the main contributing food categories were flavoured fermented milk products and fine bakery wares.

Using the refined non brand-loyal assessment exposure scenario, exposure estimates for all population groups were below the ADI at the mean and the high level. The main contributing food categories for adults and the elderly were fine bakery wares, flavoured drinks and sauces. For children and adolescents, the main contributing food categories were fine bakery wares and flavoured drinks while for toddlers, flavoured fermented milk products and fine bakery wares were the main contributing food categories.

The overall results of the present refined exposure assessment based on reported use levels were lower compared to the ones from the previous exposure assessment performed by the ANS Panel in 2010 (EFSA, 2010a).

The present exposure estimates are based on individual food consumption data available in the EFSA Comprehensive Database. Some food categories are not referenced in the EFSA Comprehensive Database (e.g. edible cheese rind, batters, *mostarda di frutta*, casings, coatings, decorations for meat) and were therefore not included in the present estimate. Nevertheless, the food consumption data available for the present assessment are more detailed compared to the data used in the previous exposure assessment (EFSA, 2010a). As a consequence, some food items could be removed from the present exposure estimates (e.g. chocolate milk and malt products), where the use of curcumin is not authorised. The use of consumption data at individual level using refined food codes could contribute to the decrease in the exposure estimates of curcumin from its use as a food additive.

Use data received from industry covered 52 out of the 57 food categories in which curcumin is authorised, indicating that curcumin is widely used in these food categories. For the five remaining food categories, no data were received. In addition, these five food categories were not taken into account in the present estimates as no FoodEx codes are available in the EFSA Comprehensive Database. The actual values on curcumin use levels were therefore used for the majority of the foods in the present assessment.

Depending on the food category, the reported use data received by EFSA in 2013 were lower or higher compared to the reported use levels used in the previous assessment (EFSA, 2010a). Reported use levels of flavoured fermented milk products, which are main contributors to the mean exposure for toddlers were now lower compared to the previous estimates (70 mg/kg at the maximum and 19 mg/kg at the typical mean instead of 150 mg/kg). Lower use levels were also reported for edible ices and desserts. Other contributing food categories had higher reported use levels: heat-treated processed meat, potato-, cereal-, flour- or starch-based snacks and processed nuts. These food categories were minor contributors to the total intake of curcumin as a food additive.

Analytical data on curcumin were submitted by Member States as well. However, only a few food categories in which curcumin is authorised were covered by these analytical data. In the majority of the reported results, the levels of curcumin were not detected (< LOD). The few quantified results were below the use data reported by industry and the current exposure estimates were solely based on use data provided by industry. Therefore, the refined exposure estimates might represent an overestimate.

It should be noted that in Regulation 438/2013 amending Annex II of Regulation (EC) No 1333/2008, MPLs were set for fish paste and crustacean paste and smoked fish (100 mg/kg) instead of the previous *QS* authorisation of curcumin in these foods.

Furthermore, it is possible that curcumin (E 100) is not currently used in all food items of fine bakery wares, flavoured drinks and flavoured milk food categories which were estimated to be main contributors to the total exposure to curcumin (E 100) in all three scenarios for all population groups. It should be noted that no restrictions/exceptions are set by the Regulation (EC) No 1333/2008, Annex II for these food categories, therefore the whole category was considered for the exposure assessment. However, FoodEx classification system includes many products within those food categories and it can be assumed that curcumin (E 100) is unlikely to be used in all those food products. This may particularly be the case for flavoured drinks when considering the large set of analytical data (n=228) and to a lesser extent also for flavoured milk products with a very limited number of analytical data (n=2) where no samples had levels above the limit of detection (i.e. non-detected levels). Therefore, if this assumption is verified, the exposure estimates calculated according to the above mentioned scenarios are likely to be overestimates for those food categories, particularly in the brand-loyal consumer scenario where the highest reported use level is taken into account. EFSA notes that the current legislation probably does not reflect the real uses of curcumin and that it would benefit from clarifications through restrictions/exceptions of the authorisations of this food additive in food categories by the EC.

In addition, consumption data on turmeric as a spice and on curry powder were available from the EFSA Comprehensive Database. The intake of curcumin from turmeric (*Curcuma longa*) as used as a spice and in curry powder and curry sauces was therefore included in the present estimates.

According to Tayyem et al. (2006), turmeric powder contains from 0.58 % up to 3.14 % of dry weight as curcumin (mean value 1.51 %), while curry powders contain relatively small amounts of curcumin in the spice mix: 0.05 % up to 0.58 % (mean value 0.28 %). The intake of curcumin from curry sauces was derived from the percentage of turmeric in curry powder using a dilution factor of 10 % of curry powder in the curry sauce (estimation according to recipes from the website marmiton.fr, visited March 2014). The resulting intakes of curcumin from natural sources (turmeric, curry powder and curry sauces) are presented in Table 8 showing the total intake of curcumin from both food additive use and from natural sources. The total intake of curcumin from both food additive use and from natural sources for consumers only was also estimated, and is shown in Appendix E.

Table 8: Summary of anticipated exposure to curcumin (E 100) from both food additive use and natural sources by population group (mg/kg bw/day, min-max across the dietary surveys)

	Toddlers (12-35 months)	Children (3-9 years)	Adolescents (10-17 years)	Adults (18-64 years)	The elderly (> 65 years)
Estimated exposure using brand-loyal scenario					
• Mean	0.4 – 2.0	0.6 – 1.6	0.2 – 0.9	0.2 – 0.6	0.1 – 0.4
• High level (95 th percentile)	1.4 – 3.3	1.2 – 3.4	0.7 – 2.3	0.4 – 1.5	0.3 – 0.9
Estimated exposure from natural sources					
• Mean	0 – 1.0x10 ⁻⁶	0 – 1.4x10 ⁻⁵	0 – 1.1x10 ⁻⁵	0 – 2.1x10 ⁻⁵	0 – 6.9x10 ⁻⁷
• High level (95 th percentile)	0	0 – 9.2x10 ⁻⁶	0 – 5.9x10 ⁻⁶	0 – 0.1x10 ⁻³	0 – 4.1x10 ⁻⁶
Estimated exposure of curcumin from both food additive use and natural sources					
• Mean	0.4 – 2.0	0.6 – 1.6	0.2 – 0.9	0.2 – 0.6	0.1 – 0.4
• High level (95 th percentile)	1.4 – 3.3	1.2 – 3.4	0.7 – 2.3	0.4 – 1.5	0.3 – 0.9

The intake of curcumin from natural sources was minor compared to the total intake of curcumin, and did not affect the overall result regarding the exceedance of the ADI in any of the population groups. Exposure estimates for all population remained the same even when the additional intake of curcumin from natural sources was taken into account. It should be noted however that using consumption data to estimate the intake via spices is uncertain and very likely to underestimate real exposure.

6. 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 were already presented in the sections above and are summarised below:

Table 9: Qualitative evaluation of influence of uncertainties

Sources of uncertainties	Direction ^(a)
Consumption data: different methodologies/representativeness/under reporting/misreporting/no portion size standard	+/-
Consumption data: food categories not available in the FoodEx nomenclature not considered/ estimation of curcumin from spices / whole food categories taken into account when restrictions to food categories not available in the FoodEx nomenclature	+/-
Use of data from food consumption survey of few days to estimate long-term (chronic) exposure	+
Correspondence of reported use levels to the food items in the EFSA Comprehensive Food Consumption Database: uncertainties on which precise types of food the use levels refer to	+/-
Use of MPLs applied to all food categories	+
Concentration data: reported use levels considered applicable for all items within the entire food category / reported use levels higher than analytical data	+
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 curcumin (E 100) and concluded that overall, uncertainty could lead to an overestimation of the calculated exposure estimates.

CONCLUSIONS

The current exposure estimates for curcumin (E 100) provide an update of the exposure assessment performed in 2010 (EFSA, 2010a).

EFSA concluded that for adults and the elderly, exposure estimates were lower than those reported in the previous opinion of the ANS Panel in 2010 (EFSA, 2010a). The current exposure estimates for these two population groups were below the ADI of 3 mg/kg bw/day both at the mean and at the high level (95th percentile) considering all scenarios. Adolescents' exposure estimates based on reported use levels (refined estimated exposure scenarios) were also below the ADI both at the mean and at the high level of exposure. For children and toddlers, exposure estimates were similar to the previous EFSA opinion at the mean and high level of the regulatory maximum level exposure assessment scenario. Using the refined estimated exposure scenarios, exposure estimates decreased compared to the previous EFSA opinion but still exceeded the ADI at the high level of the brand-loyal scenario at the upper end of the exposure range (i.e. in one country for both toddlers and children; Appendix D). The main contributing food categories for all scenarios were flavoured drinks and fine bakery wares for children, adolescents, adults and the elderly while for toddlers, the main contributing food categories were flavoured fermented milk products and fine bakery wares.

Intake of curcumin from natural sources was minor compared to the total intake of curcumin and did not affect the overall result in any of the population groups. Exposure estimates for all population groups remained the same when the additional intake of curcumin from natural sources was taken into account.

Use levels of curcumin (E 100) reported by industry cover the majority of the authorised uses of curcumin as a food additive, indicating that curcumin is widely used in these food categories.

EFSA noted that it might be unlikely that curcumin (E 100) is currently used in all food items of fine bakery wares, flavoured drinks and flavoured milk products food categories which were estimated to be main contributors to the total exposure to curcumin (E 100) for all three scenarios. This might

particularly be the case for flavoured drinks when considering the large set of analytical data (n=228) and to a lesser extent also for flavoured milk products with a very limited number of analytical data (n=2) where no samples had levels above the limit of detection (i.e. non-detected levels). Therefore, if this assumption is verified, the exposure estimates calculated according the above mentioned scenarios are likely to be overestimates for those food categories, particularly in the brand-loyal consumer scenario where the highest reported level is taken into account.

DOCUMENTATION PROVIDED TO EFSA

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2. International Chewing Gum Association (ICGA). Data on use levels of curcumin (E 100). Submitted on 26 September 2013.
3. Natural Food Colours Association (NATCOL). Data on use levels of curcumin (E 100). Submitted on 11 October 2013.
4. Private company. Data on use levels of curcumin (E 100). Submitted on 4 July 2014.
5. Analytical data provided by Members States in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2013).

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APPENDICES

Appendix A. Summary of reported use levels of curcumin (E 100) provided by industry (mg/l or mg/kg as appropriate)

FCS Category No	FCS Food category	MPL	Restrictions/exception	Total number of data	Reported use levels from industry			Information provided by	Comments	
					Number of data	Typical mean (range)	Highest maximum level			
1.4	Flavoured fermented milk products including heat treated products	150		8	8	19 (9-20)	70	NATCOL		
1.6.3	Other creams	150	only flavoured creams	3	2 (1 NP)	23 (15-30)	150	NATCOL	without NP, mean typical=30	
					1	40	40	FDE		
1.7.1	Unripened cheese excluding products falling in category 16	150	only flavoured unripened cheese	2	2 (1 NP)	25 (20-30)	150	NATCOL	without NP, mean typical=30	
1.7.5	Processed cheese	100	only flavoured processed cheese	4	4 (1 NP)	20 (10-30)	100	NATCOL	without NP, mean typical=23	
1.7.6	Cheese products (excluding products falling in category 16)	100	only flavoured unripened products	2	2 (1 NP)	25 (20-30)	100	NATCOL		
2.2.2	Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions	QS	excluding reduced fat butter	3	2	18 (6-30)	250	NATCOL		
					1	3	3	FDE		
3	Edible ices	150		20	10 (1 NP)	40 (15-120)	150 (NP)	NATCOL	without NP, mean typical=31	
					8	23 (3-100)	120	FDE		
					2	23 (6.5-40)	100	Private company		

FCS Category No	FCS Food category	MPL	Restrictions/exception	Total number of data	Reported use levels from industry			Information provided by	Comments
					Number of data	Typical mean (range)	Highest maximum level		
4.2.4.1	Fruit and vegetable preparations excluding compote	200	only mostarda di frutta	1	1	60	200	NATCOL	
4.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EEC	QS	except chestnut puree	3	3 (1 NP)	17 (10-20)	50	NATCOL	without NP, mean typical=20
4.2.5.3	Other similar fruit or vegetable spreads	QS	except <i>crème de pruneaux</i>	1	1 NP	50	100	NATCOL	1 value on a NP/ proposal to take use levels of food category 4.2.5.2 because the value is on a NP
4.2.6	Processed potato products	QS	only dried potato granules and flakes	1	1	100	200	FDE	
5.2	Other confectionery including breath refreshing microsweets	300	except candied fruit and vegetables	31	25 (1 NP)	87 (15-150 (NP))	300	NATCOL	
					6	60 (14-110)	160	FDE	
5.2	Other confectionery including breath refreshing microsweets	200	only candied fruit and vegetables	3	2	125 (100-150)	200	NATCOL	
					1	40	80	FDE	
5.3	Chewing gum	300		6	4 (2 NP)	75 (60-100)	300	NATCOL	without NP, mean typical=80
					1	19	40	FDE	

FCS Category No	FCS Food category	MPL	Restrictions/exception	Total number of data	Reported use levels from industry			Information provided by	Comments
					Number of data	Typical mean (range)	Highest maximum level		
					1	16.6	300*	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)	
5.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	500	only decorations, coatings and sauces, except fillings	16	4 (1 NP)	105 (50-200)	500	NATCOL	
					10	70 (20-250)	400	FDE	
					2	95 (90-100)	450	Private company	
5.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	300	only fillings	3	2	40 (30-50)	300	NATCOL	
					1	85	150	FDE	
7.2	Fine bakery wares	200		7	5	61	200	NATCOL	General typical

FCS Category No	FCS Food category	MPL	Restrictions/exception	Total number of data	Reported use levels from industry			Information provided by	Comments
					Number of data	Typical mean (range)	Highest maximum level		
						(2-150)			mean=52
					1 NP	2	5	FDE	
					1	4	8	Private company	
8.2.1	Non heat treated processed meat	20	only sausages	2	2	15 (10-20)	20	NATCOL	
8.2.1	Non heat treated processed meat	QS	only <i>pasturmas</i>						no use data reported on that food/use data of the same food category 8.2.1
8.2.2	Heat treated processed meat	20	only sausages, patés and terrines	4	3	17 (10-20)	20	NATCOL	for pâtés and terrines / General typical mean=18
					1	20	20	FDE	
8.2.3	Casings and coatings and decorations for meat	500	only decorations and coatings except edible external coating of <i>pasturmas</i>	1	1	300	500	NATCOL	
8.2.3	Casings and coatings and decorations for meat	QS	only edible casings	4	3	233 (50-350)	10000	NATCOL	
					1	400	400	FDE	
9.2	Processed fish and fishery products including mollusks and crustaceans	500	only surimi and similar products and salmon substitutes	1	1	50	500	NATCOL	
9.2	Processed fish and fishery products including mollusks and crustaceans	100	only fish paste and crustacean paste	3	3	40 (20-80)	300	NATCOL	
9.2	Processed fish and fishery products including mollusks and crustaceans	250	only precooked crustacean	2	1	20	250	NATCOL	General typical mean=60
					1	100	100	FDE	

FCS Category No	FCS Food category	MPL	Restrictions/exception	Total number of data	Reported use levels from industry			Information provided by	Comments	
					Number of data	Typical mean (range)	Highest maximum level			
9.2	Processed fish and fishery products including mollusks and crustaceans	100	only smoked fish	1	1	20	200	NATCOL		
9.3	Fish roe	300	except Sturgeons' eggs (Caviar)	1	1	20	300	NATCOL		
12.2.2	Seasonings and condiments	500	only seasonings, for example curry powder, tandoori	5	4 (1 NP)	306 (100-500)	500	NATCOL	without NP, mean typical=325	General typical mean=249
					1	20	40	FDE		
12.4	Mustard	300		3	2	100	300	NATCOL	General typical mean=73	
					1	20	40	FDE		
12.5	Soups and broths	50		6	5	22 (10-40)	50	NATCOL	General typical mean=21	
					1	15	30	FDE		
12.6	Sauces	500	including pickles, relishes, chutney and picalilli; excluding tomato-based sauces	12	5	84 (20-200)	500	NATCOL	General typical mean=131	
					7	166 (4-440)	480	FDE		
12.9	Protein products, excluding products covered in category 1.8	100	only meat and fish analogues based on vegetable proteins	1	1 NP	30	50	NATCOL		
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	50		1	1 NP	30	50	NATCOL	only 1 value on a NP	

FCS Category No	FCS Food category	MPL	Restrictions/exception	Total number of data	Reported use levels from industry			Information provided by	Comments	
					Number of data	Typical mean (range)	Highest maximum level			
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		1	1 NP	30	50	NATCOL	only 1 value on a NP	
14.1.4	Flavoured drinks	100	excluding chocolate milk; malt products	18	7 (1 NP)	15 (7-30)	100	NATCOL	without NP, mean typical=16	General typical mean=15
					11 (10 NP)	19 (10-20)	65 (NP)	FDE	without NP, mean typical=10	
14.2.3	Cider and perry	200	excluding <i>cidre bouché</i>	1	1	50	100	NATCOL		
14.2.4	Fruit wine and made wine	200	Excluding wino owocowe markowe	1	1	30	100	NATCOL		
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.	2	2 (1 NP)	25 (10-40)	150	NATCOL	without NP, mean typical=40	
14.2.7.1	Aromatised wines	200	Except <i>americano</i> , <i>bitter vino</i>	2	2	25 (10-40)	200	NATCOL		
14.2.7.1	Aromatised wines	100	only <i>americano</i> , <i>bitter vino</i>	1	1	40	100	NATCOL		
14.2.7.2	Aromatised wine-based drinks	200	except <i>bitter soda</i> , <i>sangria</i> , <i>claria</i> , <i>zurra</i>	1	1	40	100	NATCOL		

FCS Category No	FCS Food category	MPL	Restrictions/exception	Total number of data	Reported use levels from industry			Information provided by	Comments
					Number of data	Typical mean (range)	Highest maximum level		
14.2.7.2	Aromatised wine-based drinks	100	only <i>bitter soda</i>	1	1	40	100	NATCOL	
14.2.7.3	Aromatised wine-product cocktails	200		3	3 (1 NP)	20 (10-40)	200	NATCOL	without NP, mean typical=25
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 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 niskalkoholowe and aromatyzowane wino owocowe niskalkoholowe	3	3 (1 NP)	23 (10-50)	200	NATCOL	without NP, mean typical=30
15.1	Potato-, cereal-, flour- or starch-based snacks	100	excluding extruded or expanded savoury snack products	7	2	30	100	NATCOL	Not possible to distinct the different forms of snacks. Therefore entire food category 15.1 has a maximum level of 200 mg/kg / General typical mean=72
					5	65 (0-100)	100	FDE	
15.1	Potato-, cereal-, flour- or starch-based snacks	200	only extruded or expanded savoury snack products	6	2	50 (30-70)	200	NATCOL	
					4	114 (75-160)	200	FDE	
15.2	Processed nuts	100	only savoury coated	5	3	30 (20-	100	NATCOL	General typical

FCS Category No	FCS Food category	MPL	Restrictions/exception	Total number of data	Reported use levels from industry			Information provided by	Comments	
					Number of data	Typical mean (range)	Highest maximum level			
			nuts			50)			mean=40	
					2	54 (7-100)	100	FDE		
16	Desserts excluding products covered in category 1, 3 and 4	150		14	9	17 (7-20)	147*	NATCOL	*One value of 147 mg/kg: This max. level is only contained in one product sold in one single EU country therefore use of the 2nd maximum level (65)	General typical mean=16
					5 (3 NP)	11 (2-20)	65	FDE	without the NP, mean typical =20	
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms	300		3	3 (2 NP)	140 (70-200)	300	NATCOL	Not possible to distinct the different forms of food supplements. Therefore entire food category 17 has a level of 300 mg/kg as a maximum / General typical	
17.2	Food supplements supplied in a liquid form	100		2	2 (1 NP)	13 (10-15)	100	NATCOL		
17.3	Food supplements supplied in a syrup-type or chewable form	300	only solid food supplements	2	2 (1 NP)	45 (20-70)	200	NATCOL		

FCS Category No	FCS Food category	MPL	Restrictions/exception	Total number of data	Reported use levels from industry			Information provided by	Comments
					Number of data	Typical mean (range)	Highest maximum level		
17.3	Food supplements supplied in a syrup-type or chewable form	100	only liquid food supplements	2	2 (1 NP)	13 (10-15)	100	NATCOL	mean=60

Appendix B. Summary of analytical results of curcumin (E 100) provided by Member States (mg/l or mg/kg as appropriate)

FCS Category No	food category	MPL	Total number of data	Number of left-censored data	Range	All data				Number of positive values	Positive values			
					LOD	min	median	mean	max		min	median	mean	max
01.4	Flavoured fermented milk products including heat-treated products	150	2	2	8	8	8	8	8	-				
03	Edible ices	150	34	30	0.011-10	0.011	0.011	0.77	14.63	4	0.18	0.56	3.98	14.63
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC[11] (excluding products from food category 13.1.5)	50	1	1	8	8	8	8	8	-				
14.1.4	Flavoured drinks – excluding chocolate milk and malt products	100	228	228	8	8	8	8	8	-				

Appendix C. Concentration levels of curcumin (E 100) used in the refined exposure scenarios (mg/l or mg/kg as appropriate)

FCS Category No	FCS Food category	MPL	Concentration levels used in the refined exposure assessment		Comments
			Mean	Maximum	
01.4	Flavoured fermented milk products including heat treated products	150	19	70	Reported use levels
01.6.3	Other creams	150	-	-	Not taken into account (overestimation by using FoodEx codes)
01.7.1	Unripened cheese excluding products falling in category 16	150	30	150	Reported use levels
01.7.3	Edible cheese rind	QS	-	-	Not taken into account (no corresponding FoodEx code/no use data reported)
01.7.5	Processed cheese	100	23	100	Reported use levels
01.7.6	Cheese products (excluding products falling in category 16)	100	-	-	Not taken into account (no corresponding FoodEx code)
02.1	Fats and oils essentially free from water (excluding anhydrous milkfat)	QS	-	-	Not taken into account (no use data reported)
02.2.2	Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions	QS	13	250	Reported use levels
03	Edible ices	150	27	120	Reported use levels
04.2.4.1	Fruit and vegetable preparations excluding compote – only <i>mostarda di frutta</i>	200	-	-	Not taken into account (no corresponding FoodEx code)
04.2.4.1	Fruit and vegetable preparations excluding compote – only seaweed based fish roe analogues	50	-	-	Not taken into account (no corresponding FoodEx code/no use data reported)
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EEC	QS	20	50	Reported use levels
04.2.5.3	Other similar fruit or vegetable spreads	QS	20	50	Reported use levels
04.2.6	Processed potato products	QS	100	200	Reported use levels
05.2	Other confectionery including breath refreshing microsweets – except candied fruits and vegetables	300	80	300	Reported use levels
05.2	Other confectionery including breath refreshing microsweets – only candied fruits and vegetables	200	97	200	Reported use levels

FCS Category No	FCS Food category	MPL	Concentration levels used in the refined exposure assessment		Comments
			Mean	Maximum	
05.3	Chewing gum	300	16.6	300	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	300	-	-	Not taken into account (no corresponding FoodEx code)
06.6	Batters	500	-	-	Not taken into account (no corresponding FoodEx code/no use data reported)
07.2	Fine bakery wares	200	52	200	Reported use levels
08.2.1	Non heat treated processed meat – only sausages	20	15	20	Reported use levels
08.2.1	Non heat treated processed meat - only <i>pasturmas</i>	QS	15	20	Reported use levels: no use data reported, use of food category 08.2.1 levels
08.2.2	Heat treated processed meat – only sausages, pâtés and terrines	20	18	20	Reported use levels
08.2.3	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 code)
08.2.3	Casings and coatings and decorations for meat – only edible casings	QS	-	-	Not taken into account (no corresponding FoodEx code)
08.2.3	Casings and coatings and decorations for meat – only edible external coating of <i>pasturmas</i>	QS	-	-	Not taken into account (no corresponding FoodEx code/no use data reported)
09.2	Processed fish and fishery products including mollusks and crustaceans – only surimi and similar products and salmon substitutes	500	50	500	Reported use levels
09.2	Processed fish and fishery products including mollusks and crustaceans – only fish paste and crustaceans paste	100	40	100	Reported use levels
09.2	Processed fish and fishery products including mollusks and crustaceans – only precooked crustacean	250	60	250	Reported use levels

FCS Category No	FCS Food category	MPL	Concentration levels used in the refined exposure assessment		Comments
			Mean	Maximum	
09.2	Processed fish and fishery products including mollusks and crustaceans – only smoked fish	100	20	100	Reported use levels
09.3	Fish roe	300	20	300	Reported use levels
12.2.2	Seasonings and condiments	500	249	500	Reported use levels
12.4	Mustard	300	73	300	Reported use levels
12.5	Soups and broths	50	21	50	Reported use levels
12.6	Sauces	500	131	500	Reported use levels
12.9	Protein products, excluding products covered in category 1.8	100	30	50	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	30	50	Reported use levels
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	30	50	Reported use levels
14.1.4	Flavoured drinks	100	15	100	Reported use levels
14.2.3	Cider and perry	200	50	100	Reported use levels
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	40	150	Reported use levels
14.2.7.1	Aromatised wines – except <i>americano</i> , <i>bitter vino</i>	200	25	200	Reported use levels
14.2.7.1	Aromatised wines – only <i>americano</i> , <i>bitter vino</i>	100	40	100	Reported use levels
14.2.7.2	Aromatised wine-based drinks – except <i>bitter soda</i> , <i>sangria</i> , <i>claria</i> , <i>zurra</i>	200	40	100	Reported use levels
14.2.7.2	Aromatised wine-based drinks – only <i>bitter soda</i>	100	40	100	Reported use levels
14.2.7.3	Aromatised wine-product cocktails	200	25	200	Reported use levels
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol	200	30	200	Reported use levels
15.1	Potato-, cereal-, flour- or starch-based snacks – excluding	100	72	200	Reported use levels

FCS Category No	FCS Food category	MPL	Concentration levels used in the refined exposure assessment		Comments
			Mean	Maximum	
	extruded or expanded savoury snack products				
15.1	Potato-, cereal-, flour- or starch-based snacks – only extruded or expanded savoury snack products	200			
15.2	Processed nuts	100	40	100	Reported use levels
16	Desserts excluding products covered in category 1, 3 and 4	150	18	65	Reported use levels
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms	300	60	300	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 curcumin (E 100) from its use as a food additive for MPL scenario and refined exposure scenarios per population group and survey: mean and high level (mg/kg bw/day)

	Number of subjects	MPL scenario		Non brand-loyal scenario		Brand-loyal scenario	
		Mean	High level	Mean	High level	Mean	High level
Toddlers							
Belgium (Regional Flanders)	36	3.9		0.8		2.0	
Bulgaria (NUTRICHILD)	428	1.1	2.8	0.3	0.6	0.8	2.0
Germany (DONALD 2006_2008)	261	1.2	3.1	0.3	0.7	0.7	1.7
Spain (enKid)	17	1.7		0.3		0.8	
Finland (DIPP 2003_2006)	497	0.9	3.2	0.1	0.5	0.4	1.4
Italy (INRAN SCAI 2005_06)	36	1.0		0.2		0.6	
Netherlands (VCP kids)	322	3.4	7.2	0.6	1.2	1.5	3.3
Children							
Belgium (Regional Flanders)	625	3.2	6.7	0.6	1.2	1.6	3.4
Bulgaria (NUTRICHILD)	433	1.5	3.5	0.3	0.7	1.0	2.3
Czech Republic (SISP04)	389	1.9	4.2	0.4	0.8	1.1	2.9
Germany (DONALD 2006_2008)	660	1.9	3.9	0.4	0.8	1.0	2.4
Denmark (Danish Dietary Survey)	490	1.5	2.8	0.3	0.5	0.9	1.9
Spain (enKid)	156	1.6	4.0	0.3	0.8	0.8	2.0
Spain (NUT INK05)	399	1.5	3.2	0.4	0.7	0.8	1.8
Finland (DIPP 2003_2006)	933	1.3	2.9	0.3	0.5	0.6	1.4
Finland (STRIP)	250	2.5	4.1	0.6	0.9	1.3	2.5
France (INCA2)	482	1.7	3.2	0.4	0.7	0.9	1.8
Greece (Regional Crete)	839	1.1	2.3	0.3	0.5	0.7	1.5
Italy (INRAN SCAI 2005_06)	193	0.9	2.0	0.2	0.5	0.6	1.2
Latvia (EFSA TEST)	189	1.4	3.3	0.4	0.8	0.9	2.2
Netherlands (VCP kids)	957	3.0	6.1	0.6	1.0	1.3	2.7
Sweden (NFA)	1473	2.9	5.6	0.6	1.1	1.4	2.8
Adolescents							
Belgium (Diet National 2004)	584	1.1	2.5	0.3	0.6	0.7	1.8
Cyprus (Childhealth)	303	0.3	1.0	0.1	0.2	0.2	0.7
Czech Republic (SISP04)	298	1.4	3.3	0.3	0.6	0.9	2.3
Germany (National Nutrition Survey II)	1011	0.9	2.3	0.2	0.5	0.6	1.5
Denmark (Danish Dietary Survey)	479	1.1	2.5	0.2	0.4	0.7	1.8
Spain (AESAN FIAB)	86	0.5	1.1	0.1	0.3	0.3	0.8
Spain (enKid)	209	1.0	2.3	0.2	0.5	0.6	1.4
Spain (NUT INK05)	651	0.8	1.9	0.2	0.4	0.5	1.0
France (INCA2)	973	0.8	1.8	0.2	0.4	0.5	1.1
Italy (INRAN SCAI 2005_06)	247	0.5	1.2	0.1	0.3	0.3	0.7
Latvia (EFSA TEST)	470	1.0	2.3	0.3	0.6	0.6	1.4
Sweden (NFA)	1018	1.6	3.3	0.3	0.7	0.9	1.7

	Number of subjects	MPL scenario		Non brand-loyal scenario		Brand-loyal scenario	
		Mean	High level	Mean	High level	Mean	High level
Adults							
Belgium (Diet National 2004)	1304	0.8	2.1	0.2	0.5	0.5	1.4
Czech Republic (SISP04)	1666	0.6	1.5	0.1	0.3	0.4	1.0
Germany (National Nutrition Survey II)	10419	0.7	1.7	0.2	0.4	0.5	1.1
Denmark (Danish Dietary Survey)	2822	0.5	1.3	0.1	0.2	0.3	1.0
Spain (AESAN)	410	0.4	1.1	0.1	0.2	0.3	0.6
Spain (AESAN FIAB)	981	0.3	0.9	0.1	0.2	0.2	0.6
Finland (FINDIET 2007)	1575	0.4	1.1	0.1	0.2	0.2	0.6
France (INCA2)	2276	0.6	1.2	0.1	0.3	0.3	0.7
United Kingdom (NDNS)	1724	0.7	1.4	0.2	0.3	0.4	0.9
Hungary (National Repr Surv)	1074	0.3	0.8	0.1	0.2	0.2	0.6
Ireland (NSIFCS)	958	0.5	1.2	0.1	0.3	0.3	0.7
Italy (INRAN SCAI 2005_06)	2313	0.3	0.7	0.1	0.2	0.2	0.4
Latvia (EFSA TEST)	1306	0.5	1.2	0.1	0.3	0.4	0.9
Netherlands (DNFCS 2003)	750	1.1	2.3	0.2	0.4	0.6	1.5
Sweden (Riksmaten 1997_98)	1210	0.7	1.6	0.2	0.3	0.4	1.0
The elderly							
Belgium (Diet National 2004)	1230	0.6	1.4	0.2	0.4	0.4	0.9
Germany (National Nutrition Survey II)	2496	0.5	1.2	0.1	0.3	0.4	0.9
Denmark (Danish Dietary Survey)	329	0.3	0.7	0.1	0.1	0.1	0.4
Finland (FINDIET 2007)	463	0.1	0.6	0.0	0.1	0.1	0.3
France (INCA2)	348	0.4	0.9	0.1	0.2	0.2	0.5
Hungary (National Repr Surv)	286	0.2	0.7	0.1	0.1	0.2	0.5
Italy (INRAN SCAI 2005_06)	518	0.2	0.5	0.0	0.1	0.1	0.3

Appendix E. Summary of anticipated exposure to curcumin (E 100) from both food additive use (following scenario 2) and natural sources by population group (mg/kg bw/day, min-max across the dietary surveys), for consumers only

	Toddlers (12-35 months)	Children (3-9 years)	Adolescents (10-17 years)	Adults (18-64 years)	The elderly (> 65 years)
Estimated exposure using scenario 2					
• Mean	0.4 – 2.0	0.6 – 1.6	0.2 – 0.9	0.2 – 0.6	0.1 – 0.4
• High level (95 th percentile)	1.4 – 3.3	1.2 – 3.4	0.7 – 2.3	0.4 – 1.5	0.3 – 0.9
Estimated exposure from natural sources					
• Mean	$2.6 \cdot 10^{-5} - 2.9 \cdot 10^{-5}$	$1.3 \cdot 10^{-5} - 0.5 \cdot 10^{-3}$	$6.7 \cdot 10^{-6} - 0.3 \cdot 10^{-3}$	$4.0 \cdot 10^{-6} - 0.1 \cdot 10^{-3}$	$4.4 \cdot 10^{-6} - 0.1 \cdot 10^{-3}$
• High level (95 th percentile)	$4.6 \cdot 10^{-5} - 4.8 \cdot 10^{-5}$	$3.0 \cdot 10^{-5} - 0.9 \cdot 10^{-3}$	$1.6 \cdot 10^{-5} - 0.5 \cdot 10^{-3}$	$6.1 \cdot 10^{-6} - 0.4 \cdot 10^{-3}$	$1.4 \cdot 10^{-5} - 0.1 \cdot 10^{-3}$
Estimated exposure of curcumin from both food additive use and natural sources					
• Mean	0.4 – 2.0	0.6 – 1.6	0.2 – 0.9	0.2 – 0.6	0.1 – 0.4
• High level (95 th percentile)	1.4 – 3.3	1.2 – 3.4	0.7 – 2.3	0.4 – 1.5	0.3 – 0.9

ABBREVIATIONS

ADI	Acceptable Daily Intake
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 Organisation
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
MPL	Maximum Permitted Level
NATCOL	Natural Food Colours Association
NOAEL	No-Observed-Adverse-Effect Level
NP	Niche product
QS	Quantum satis
SCF	Scientific Committee for Food
SCOOP	A scientific cooperation (SCOOP) task involves coordination amongst Member States to provide pooled data from across the EU on particular issues of concern regarding food safety
UK	United Kingdom
UNESDA	Union of European Soft Drinks Associations
WHO	World Health Organization