STATEMENT OF EFSA

Refined exposure assessment for Quinoline Yellow (E 104)[1]

European Food Safety Authority[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The European Food Safety Authority (EFSA) carried out an exposure assessment of Quinoline Yellow (E 104), 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 Quinoline Yellow (E 104) and concluded that, at the maximum usage levels, refined intake estimates were generally well above the Acceptable Daily Intake (ADI) of 0.5 mg/kg body weight (bw)/day. Annex II to Regulation (EC) No 1333/2008 was amended by the European Commission as regards the conditions of use such that Maximum Permitted Levels (MPLs), when not withdrawn (n = 14), were decreased by a factor of 1.1 to 50, depending on the food category, applicable from 1 June 2013 onwards. Following this, the European Commission requested EFSA to perform a refined exposure assessment for this food colour. Data on the presence of Quinoline Yellow (E 104) in foods were requested from relevant stakeholders through a call for usage and analytical data. Usage levels were provided to EFSA for 6 out of 28 food categories in which Quinoline Yellow (E 104) is authorised. In addition, 6 266 analytical results were reported. Following the amendment of Annex II to Regulation (EC) No 1333/2008, exposure estimates for Quinoline Yellow (E 104) presented in this statement were based on the currently authorised MPLs and analytical levels combined with food consumption data from the EFSA Comprehensive Food Consumption Database. Three scenarios were considered: (1) exposure estimates based on MPLs, (2) a refined brand-loyal exposure scenario and (3) a refined non-brand-loyal exposure scenario. Mean and high-level exposure estimates of Quinoline Yellow (E 104) were below the ADI for all population groups in all three scenarios.

KEY WORDS

Quinoline Yellow, E 104, dietary exposure, EFSA Comprehensive European Food Consumption Database, food colours

[1] On request from EFSA, Question No EFSA-Q-2012-00888, approved on 23 March 2015.

[2] Correspondence: fip@efsa.europa.eu

[3] Acknowledgement: EFSA wishes to thank Polly Boon, Jean-Charles Leblanc and Oliver Lindtner, for the preparatory work on this scientific output and EFSA staff: Davide Arcella, Petra Gergelova, Alexandra Tard and Stavroula Tasiopoulou, for the support provided to this scientific output. EFSA acknowledges those European competent authorities, food industry and other stakeholders that provided occurrence data (usage and analytical data) on Quinoline Yellow (E 104) in food and beverages, and supported the data collection for the Comprehensive European Food Consumption Database.

Suggested citation: EFSA (European Food Safety Authority), 2015. Refined exposure assessment for Quinoline Yellow (E 104). EFSA Journal 2015;13(3):4070, 33 pp., doi:10.2903/j.efsa.2015.4070

Available online: www.efsa.europa.eu/efsajournal

SUMMARY

Following an internal mandate proposed by the European Food Safety Authority (EFSA) to the Food Ingredients and Packaging (FIP) Unit for producing EFSA statements with refined exposure calculations for food colours with possible exceedance of the Acceptable Daily Intake (ADI), EFSA carried out a refined exposure assessment for Quinoline Yellow (E 104), taking into account additional information on its use in foods and beverages.

Quinoline Yellow (E 104) is a quinophthalone dye authorised as a food additive in the European Union (EU) for use in foods in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives, as amended. It was previously evaluated by the Joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) in 1975, 1978 and 1984, and by the EU Scientific Committee for Food (SCF) in 1984. Both committees established an ADI of 0–10 mg/kg body weight (bw)/day.

In 2009, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) adopted a scientific opinion on the re-evaluation of Quinoline Yellow (E 104) as a food additive. The ANS Panel concluded that, at the maximum usage levels, refined intake estimates were generally well above the ADI of 0.5 mg/kg bw/day established by the Panel. Following conclusions of that opinion, Annex II to Regulation (EC) No 1333/2008 was amended by the European Commission (EC) as regards the conditions of use (Commission Regulation (EU) No 232/2012)[4] such that Maximum Permitted Levels (MPLs), when not withdrawn (n = 14), were decreased by a factor of 1.1 to 50, depending on the food category, applicable from 1 June 2013 onwards.

In 2011, JECFA established a new temporary ADI of 0–5 mg/kg bw/day and the previously established ADI of 0–10 mg/kg bw/day was withdrawn.

The present statement provides an exposure assessment of Quinoline Yellow (E 104) based on individual consumption data from the EFSA Comprehensive European Food Consumption Database, current MPLs and information on the reported analytical results of Quinoline Yellow (E 104) in foods, provided to EFSA Member States, following an EFSA call for data[5] launched in March 2013. Three exposure scenarios were considered: (1) based on MPLs (*regulatory maximum level exposure assessment*—MPL scenario), (2) a brand-loyal exposure scenario assuming long-term exposure to Quinoline Yellow (E 104) at the maximum reported analytical level for one food category and mean analytical levels for other food categories and (3) a non-brand-loyal exposure scenario assuming a long-term exposure to Quinoline Yellow (E 104) at the mean reported analytical levels for all foods.

The *regulatory maximum level exposure assessment* scenario showed exposure estimates below the ADI of 0.5 mg/kg bw/day for all population groups, both at the mean and at the high level. The highest mean dietary exposure to Quinoline Yellow (E 104) was observed in toddlers (up to 0.23 mg/kg bw/day), and the highest 95th percentile exposure was in toddlers and children (up to 0.40 mg/kg bw/day).

The refined exposure scenarios also showed considerably low exposure for all population groups at both mean and high level with estimates below the ADI of 0.5 mg/kg bw/day. The highest mean dietary exposure to Quinoline Yellow (E 104) for the brand-loyal and non-brand-loyal scenarios was observed in toddlers with values of up to 0.15 mg/kg bw/day and up to 0.03 mg/kg bw/day,

[4] Commission Regulation (EU) No 232/2012 of 16 March 2012 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the conditions of use and the use levels for Quinoline Yellow (E 104), Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124). OJ L 78, 17.03.2012, p. 12.

[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: http://www.efsa.europa.eu/en/dataclosed/call/130327.htm

respectively, whereas the highest 95th percentile exposure was in children, with values of up to 0.29 mg/kg bw/day and up to 0.05 mg/kg bw/day, respectively.

For the MPL scenario, the mean and the 95th percentile exposure estimates of the current exposure assessment of Quinoline Yellow (E 104) are estimated to be much lower than in the evaluation carried out in 2009. In addition, for refined scenarios, the current exposure estimates of Quinoline Yellow (E 104) based on analytical levels are lower than those in the previous assessment for both the mean and the high exposure levels. These differences are the result of lower MPLs set out in 2012, different approaches used for refined scenarios, different data submitted, more food consumption data being available and a detailed nomenclature of foods categories, thus allowing a detailed selection of foods that can contain Quinoline Yellow (E 104).

In conclusion, considering the MPL and refined exposure scenarios, the mean and high-level exposure estimates of Quinoline Yellow (E 104) are below the ADI for all population groups.

TABLE OF CONTENTS

1. Introduction

1.1. Background and Terms of reference as provided by EFSA

In its letter of 26 May 2011 to the European Food Safety Authority (EFSA), the European Commission (EC) requested clarification on the outcomes of the exposure calculations undertaken by the ANS Panel in the opinions on the so-called Southampton colours (quinoline yellow[6], sunset yellow[7], ponceau 4R[8]). The Member States and stakeholders had informed the European Commission that the figures used in these exposure assessments required possibly some updating.

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

Once the necessary preparatory work to enable the realisation of the foreseen refined exposure assessments, e.g. the establishment of a correspondence table between the food classification system (FCS) of the new European legislation (Regulation (EU) No 1129/2011[9]) and that of the EFSA Comprehensive Food Consumption Database (FoodEx) had been finalised, EFSA has 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), 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 Commission 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 food classification system 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 100), 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)

1.2. Interpretation of the Terms of Reference

The aim of the present assessment is to provide a refined exposure assessment for Quinoline Yellow (E 104) from its use as a food colour using the approach adopted by the ANS Panel in July 2014 at its

[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.

52nd plenary meeting[10]. This approach is to be followed to assess the exposure as part of the safety assessment of food additives under re-evaluation with the use of the EFSA Comprehensive European Food Consumption Database (hereinafter referred to as the Comprehensive Database) and the FoodEx food classification system and taking into consideration, besides the Maximum Permitted Levels (MPLs), updated use levels reported by industry and analytical data from Member States.

1.3. Additional information

Quinoline Yellow (E 104) is a quinophthalone dye authorised as a food additive in the European Union (EU) under Annex II to Regulation (EC) 1333/2008[11], as amended[12], for use in 28 food categories, at MPLs between 10 and 300 mg/kg or mg/l.

Quinoline Yellow (E 104) has previously been evaluated by the Joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) in 1975, 1978 and 1984 (JECFA, 1975, 1978, 1984), and by the European Commission Scientific Committee for Food (SCF) in 1984 (SCF, 1984). At that time, both committees established an Acceptable Daily Intake (ADI) of 0–10 mg/kg body weight (bw)/day. In 2011, JECFA established a new temporary ADI of 0–5 mg/kg bw/day and the previously established ADI of 0–10 mg/kg bw/day was withdrawn (JECFA, 2011).

In 2009, the EFSA ANS Panel re-evaluated Quinoline Yellow (E 104) as a food additive (EFSA ANS Panel, 2009). The safety of Quinoline Yellow (E 104) was assessed on the basis of MPLs in the legislation[13] and maximum reported use levels. The ANS Panel established an ADI of 0.5 mg/kg bw/day, based on a chronic toxicity and carcinogenicity study with a reproductive toxicity phase carried out in rats.

The ANS Panel concluded that, at the maximum reported levels of use of Quinoline Yellow (E 104), refined intake estimates were generally well above the ADI of 0.5 mg/kg bw/day.

Table 1 presents the dietary exposure to Quinoline Yellow (E 104) as estimated by the ANS Panel in 2009 for two population groups: children and adults (EFSA ANS Panel, 2009).

[10] http://www.efsa.europa.eu/en/events/event/140701a-m.pdf
[11] Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 354, 31.12.2008, p. 16.
[12] Commission Regulation (EU) No 232/2012 of 16 March 2012 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the conditions of use and the use levels for Quinoline Yellow (E 104), Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124). OJ L 78, 17.3.2012, p. 1.
[13] 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 exposure to Quinoline Yellow (E 104) in children and adults as calculated in the previous ANS Panel opinion (EFSA ANS Panel, 2009) (mg/kg bw/day)

	Adult UK population (> 18 years old)	Pre-school UK children (1.5–4.5 years old, 15 kg bw)	Children EXPOCHI population (1–10 years old, 25–30 [(a)] kg bw)
Estimated exposure using MPLs			
Mean exposure	0.9	3.1	0.8–3.5
Exposure 95th [(b)] or 97.5th percentile [(c)]	2.1	7.3	1.8–9.6
Estimated exposure using maximum reported use levels			
Mean exposure	0.5	1.8	0.5–2.0
Exposure 95th [(b)] or 97.5th percentile [(c)]	1.2	4.3	1.1–4.1

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

The main contributors (> 10 %) to the total estimated mean exposure of the adult population to Quinoline Yellow (E 104) were soft drinks, fine bakery wares, fruit wines, cider and perry, and desserts (including flavoured milk products). For children, the main contributors to the total exposure to Quinoline Yellow (E 104) (> 10 %) were soft drinks, fine bakery wares, confectionery, sauces and seasonings, pickles, relishes, chutney and piccalilli and desserts (including flavoured milk products).

2. Data and methodologies

2.1. Data

2.1.1. Use and use levels of Quinoline Yellow (E 104)

MPLs of use of Quinoline Yellow (E 104) have been defined in Annex II to Regulation (EC) No 1333/2008[14] of the European Parliament and of the Council on food additives by establishing a Union list of food additives, as amended (Table 2).

Quinoline Yellow (E 104) may also be used in the form of colour lakes[14].

It should be noted that in 2012, following the conclusions of the EFSA Opinion on Quinoline Yellow (E 104) adopted in 2009 by the ANS Panel, Annex II to Regulation (EC) No 1333/2008 was amended as regards the conditions of use and the use levels for Sunset Yellow FCF (E 110), Quinoline Yellow (E 104) and Ponceau 4R (E 124) (Commission Regulation (EU) No 232/2012[15]). For Quinoline Yellow (E 104), MPLs, when not withdrawn (n = 14), were decreased by a factor of 1.1 to 50, depending on the food category, applicable from 1 June 2013 onwards, as shown in Table 2.

[14] Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 354, 31.12.2008, p. 16.
[15] Commission Regulation (EU) No 232/2012 of 16 March 2012 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the conditions of use and the use levels for Quinoline Yellow (E 104), Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124). OJ L 78, 17.03.2012, p. 12.

Table 2: MPLs of Quinoline Yellow (E 104) in foods according to Annex II to Regulation (EC) No 1333/2008

FCS Category No	Food category	Restriction/exception	MPL (mg/l or mg/kg as appropriate)	Previous MPL used in the EFSA ANS opinion (2009) (mg/l or mg/kg as appropriate)
01.4	**Flavoured fermented milk products, including heat-treated products**		10 [(a)]	150
01.6.3	**Other creams**	Only flavoured creams	10 [(a)]	150
01.7.1	**Unripened cheese excluding products falling in category 16**	Only flavoured unripened cheese	–	150
01.7.3	**Edible cheese rind**		10 [(b)]	*Quantum satis*
01.7.5	**Processed cheese**	Only flavoured processed cheese	–	100
01.7.6	**Cheese products (excluding products falling in category 16)**	Only flavoured unripened products	–	100
03	**Edible ices**		–	150
04.2.4.1	**Fruit and vegetable preparations excluding compote**	Only *mostarda di frutta*	30 [(a)]	200
04.2.5.2	**Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2001/113/EC**	Except chestnut purée	–	100
04.2.5.3	**Other similar fruit or vegetable spreads**	Except *crème de pruneaux*	–	100
05.2	**Other confectionery including breath freshening microsweets**	Except candied fruit and vegetables; traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions, i.e. weddings, communion, etc.	30 [(a)]	300
05.2	**Other confectionery including breath freshening microsweets**	Only candied fruit and vegetables	30 [(a)]	200
05.2	**Other confectionery including breath freshening microsweets**	Only traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions, i.e. weddings, communion, etc.	300 [(a)]	–
05.3	**Chewing gum**		30 [(a)]	300

FCS Category No	Food category	Restriction/exception	MPL (mg/l or mg/kg as appropriate)	Previous MPL used in the EFSA ANS opinion (2009) (mg/l or mg/kg as appropriate)
05.4	**Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4**	Only decorations, coatings and sauces, except fillings	50 (a)	500
05.4	**Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4**	Only fillings	50 (a)	300
06.6	**Batters**		50 (a)	500
07.2	**Fine bakery wares**		–	200
08.3.3	**Casings and coatings and decorations for meat**	Only decorations and coatings except edible external coating of *pasturmas*	50 (a)	500
08.3.3	**Casings and coatings and decorations for meat**	Only edible casings	10 (b)	*quantum satis*
09.2	**Processed fish and fishery products including molluscs and crustaceans**	Only fish paste and crustacean paste	–	100
09.2	**Processed fish and fishery products including molluscs and crustaceans**	Only surimi and similar products and salmon substitutes	–	500
09.3	**Fish roe**	Except Sturgeons' eggs (caviar)	200 (a)	300
12.2.2	**Seasonings and condiments**	Only seasonings, for example curry powder, tandoori	10 (b)	500
12.4	**Mustard**		10 (a)	300
12.5	**Soups and broths**		–	50
12.6	**Sauces**	Including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces	20 (c)	500
12.9	**Protein products, excluding products covered in category 1.8**	Only meat and fish analogues based on vegetable proteins	10 (a)	100
13.2	**Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)**		10 (a)	50
13.3	**Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)**		10 (a)	50

FCS Category No	Food category	Restriction/exception	MPL (mg/l or mg/kg as appropriate)	Previous MPL used in the EFSA ANS opinion (2009) (mg/l or mg/kg as appropriate)
14.1.4	**Flavoured drinks**	Excluding chocolate milk; malt products	10 [(a)]	100
14.2.3	**Cider and perry**	Excluding *cidre bouché*	25 [(c)]	200
14.2.4	**Fruit wine and made wine**		20 [(a)]	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 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	180 [(a)]	200
14.2.7.1	**Aromatised wines**	Only *americano, bitter vino*	50 [(d, e)]	100
14.2.7.1	**Aromatised wines**	Except *americano, bitter vino*	50 [(a)]	200
14.2.7.2	**Aromatised wine-based drinks**	Only *bitter soda*	50 [(f)]	100
14.2.7.2	**Aromatised wine-based drinks**	Except *bitter soda, sangria, claria, zurra*	50 [(a)]	200
14.2.7.3	**Aromatised wine-product cocktails**		50 [(a)]	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	180 [(a)]	200
15.1	**Potato-, cereal-, flour- or starch-based snacks**	Excluding extruded or expanded savoury snack products	–	100
15.1	**Potato-, cereal-, flour- or starch-based snacks**	Only extruded or expanded savoury snack products	–	200
15.2	**Processed nuts**	Only savoury-coated nuts	–	100
16	**Desserts excluding products covered in category 1, 3 and 4**		10 [(a)]	150

FCS Category No	Food category	Restriction/exception	MPL (mg/l or mg/kg as appropriate)	Previous MPL used in the EFSA ANS opinion (2009) (mg/l or mg/kg as appropriate)
17.1	**Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms**		35 (a)	300
17.2	**Food supplements supplied in a liquid form**		10 (a)	100
17.3	**Food supplements supplied in a syrup-type or chewable form**		10 (a)	–
17.3	**Food supplements supplied in a syrup-type or chewable form**	Only solid food supplements	–	300
17.3	**Food supplements supplied in a syrup-type or chewable form**	Only liquid food supplements	–	100

(a): The total quantity of E 104, E 110, E 124 and the colours in Group III shall not exceed the maximum listed for Group III.
(b): The total quantity of E 104 and the colours in Group III shall not exceed the maximum listed for Group III.
(c): The total quantity of E 104 and E 110 and the colours in Group III shall not exceed the maximum listed for Group III.
(d): In americano, E 100, E 101, E 102, E 104, E 120, E 122, E 123, E 124 are authorised individually or in combination.
(e): In bitter vino, E 100, E 101, E 102, E 104, E 110, E 120, E 122, E 123, E 124, E 129 are authorised individually or in combination.
(f): In bitter soda, E 100, E 101, E 102, E 104, E 110, E 120, E 122, E 123, E 124, E 129 are authorised individually or in combination.
FCS: Food Categorisation System

2.1.2. Reported use levels and analytical levels of Quinoline Yellow (E 104)

Most food additives in the EU are authorised at a specific MPL. However, a food additive may be used at a lower level than its MPL. Therefore, information on actual use levels is required for performing a more realistic exposure assessment, especially for those food categories for which a food additive is authorised according to *quantum satis*. Currently, Quinoline Yellow (E 104) is not authorised at *quantum satis* in any food categories (Table 2).

In the framework of Regulation (EC) No 1333/2008 on food additives and of Commission Regulation (EU) No 257/2010[16] regarding the re-evaluation of approved food additives, EFSA issued a public call[17] for food additive usage level and/or concentration[18] data on Quinoline Yellow (E 104).

Data on Quinoline Yellow (E 104), including present use and use patterns (i.e. the food categories and subcategories) and the actual use levels (typical and maximum use levels), were requested from relevant stakeholders. European food manufacturers, national food authorities, research institutions,

[16] 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.
[17] 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: http://www.efsa.europa.eu/en/data/call/130327.htm
[18] Term 'concentration' in this call for data refers to analytical data

academia, food business operators and any other interested stakeholders were invited to submit usage levels and/or analytical data on Quinoline Yellow (E 104) in foods and beverages. Data submission to EFSA followed the requirements of the Standard Sample Description for Food and Feed (EFSA, 2010a).

2.1.2.1. Summarised data on reported use levels of Quinoline Yellow (E 104) in foods provided by industry

Data (n = 17) on 6 out of the 28 food categories in which Quinoline Yellow (E 104) is authorised as a food additive were provided to EFSA by the food industry. Reported use levels of Quinoline Yellow (E 104) in foods were provided to EFSA by the International Chewing Gum Association (ICGA), the Association of the European Self-Medication Industry (AESGP) and FoodDrinkEurope (FDE).

Only usage data on four food categories in compliance with the current MPLs were taken into consideration for the exposure assessment. These usage data (n = 14) were provided by FDE for the following food categories: other confectionery (FCS food category 5.2), chewing gum (FCS food category 5.3), batters (FCS food category 6.6) and flavoured drinks (FCS food category 14.1.4).

For all other food categories in which the use of Quinoline Yellow (E 104) is authorised, the reported use levels provided through the call for data did not comply with the current MPLs and have not been considered in the exposure assessment. It was assumed that those usage data do not reflect the current exposure to Quinoline Yellow (E 104).

Usage data provided on Quinoline Yellow (E 104) in foods and beverages by industry complying with the current MPLs across the food categories are summarised in Appendix A.

2.1.2.2. Summarised data on analytical levels of Quinoline Yellow (E 104) in foods provided by Member States

Analytical results from Member States were collected through the EFSA call for data[19]. It should be noted that complete information on the methods of analysis was not provided to EFSA. In total, 6 266 analytical results were reported to EFSA by seven countries: Austria (n = 995), Cyprus (n = 109), the Czech Republic (n = 317), Germany (n = 3558), Hungary (n = 262), Ireland (n = 406) and Slovakia (n = 619). These data were mainly on flavoured drinks (FCS food category 14.1.4), other confectionery including breath freshening microsweets, (FCS food category 5.2) and fine bakery wares (FCS food category 7.2). All 20 FoodEx level 1 food categories were covered. Foods were sampled between 2001 and 2013 and were analysed during the same period of time.

In order to include only recent data, analytical results sampled before 2004 (n = 13) were excluded from the exposure assessment. Moreover, 934 analytical results expressed as qualitative were also not used, as they give only binary results (i.e. an indication of the presence or absence of the food additive in the food analysed). In total, 272 out of 934 qualitative results indicated the presence of Quinoline Yellow (E 104), most of them in edible ices and fine bakery wares.

Only 244 analytical results received from the Member States related to food items sampled in 2013, and only 96 were sampled after 1 June 2013. In the absence of more recent data, data collected before 2013 were also considered for the refined exposure assessment scenario, provided that the values were below the currently authorised MPLs of use of Quinoline Yellow (E 104).

Overall, 2 413 out of the 6 266 total analytical results reported for Quinoline Yellow (E 104) in foods were included in the exposure estimates after discarding analytical results on foods in which Quinoline Yellow (E 104) is not currently authorised and/or analytical results exceeding the current MPLs

[19] 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: http://www.efsa.europa.eu/en/data/call/130327.htm

(n = 2906), results obtained before 2004 (n = 13) and values expressed as qualitative results (n = 934). Out of this cleaned dataset (n = 2 413), analytical results of Quinoline Yellow (E 104) were not quantified (lower than the limit of quantification (LOQ)) in 469 samples and not detected (lower than the limit of detection (LOD)) in 1 566 samples and only 378 were numerical values (quantified). All analytical results came from accredited laboratories.

Samples with numerical values (above LOD/LOQ) (n = 378) pertained to the following food categories: other creams (FCS food category 1.6.3), other confectionery including breath freshening microsweets, (FCS food category 5.2), chewing gum (FCS food category 5.3), fish roe (FCS food category 9.3), sauces (FCS food category 12.6), flavoured drinks (FCS food category 14.1.4), alcoholic beverages (FCS food categories 14.2), desserts (FCS food category 16) and food supplements (FCS food category 17).

Appendix B shows the analytical results of Quinoline Yellow (E 104) in foods and beverages 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 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 by subjects' possible underreporting and/or misreporting of the consumption amounts.

2.1.3.2. Food items selected for the refined exposure assessment of Quinoline Yellow (E 104)

The food categories in which the use of Quinoline Yellow (E 104) 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). For example, for the FCS category 14.1.4, 'Flavoured drinks', the MPL of 10 mg/kg for Quinoline Yellow (E 104) was combined with consumption data on all types of non-alcoholic drinks at FoodEx level 4 with the exception of chocolate milk and malt products.

Some food categories or their restrictions/exceptions are not referenced in the EFSA Comprehensive Database and could therefore not be taken into account in the present estimate. These food categories are listed below (in ascending order of FCS code):

- 1.6.3 Other creams, only flavoured creams;
- 1.7.3 Edible cheese rind;
- 4.2.4.1 Fruit and vegetable preparations excluding compote, only *mostarda di frutta*;
- 5.2 Other confectionery including breath freshening microsweets, only traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions, i.e. weddings, communion, etc.;
- 5.4 Decorations, coatings and fillings: this category covers confectionery products generally used for decorating, coating and filling of foodstuffs, e.g. fine bakery wares, edible ices, candy

and confections. This food category is not available in the FoodEx nomenclature, but foodstuffs that are likely to be decorated, coated or filled (e.g. fine bakery wares) were included in the assessment;

- 6.6 Batters;
- 8.3.3 Casings, coatings and decorations for meat;
- 14.2.4 Fruit wine and made wine;
- 14.2.7.2 Aromatised wine-based drinks;
- 14.2.7.3 Aromatised wine-product cocktails.

For the following food categories, the restrictions that apply to the use of Quinoline Yellow (E 104) could not be taken into account, and therefore the whole food category was considered for the exposure estimates. The food categories for which this applied are listed below (in ascending order of FCS code):

- 9.3. 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. Therefore, the whole food category was taken into account;
- 14.2.3. Cider and perry, excluding *cidre bouché*: no distinction was possible between cider and *cidre bouché*; therefore, the entire food category was included in the exposure estimates;
- 17 Food supplements: it was not possible to differentiate solid, liquid or syrup-type, or chewable forms of food supplements within FoodEx codes; therefore, these three food categories were considered as a whole and the highest MPL and the highest analytical level were used in the exposure assessment.

Further refinements were made in the following food categories:

- 12.2.2 Seasonings and condiments, only seasonings, for example curry powder, tandoori: only seasonings, including spices, herbs, seasonings and extracts, and herbs and spice mixtures were considered in the exposure assessment;
- 12.6 Sauces, including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces: only condiments, chutney and pickled, savoury sauces and dressings, excluding tomato-based sauces and ketchup, were included in the exposure assessment;
- 12.9 Protein products, excluding products covered in category 1.8, only meat and fish analogues based on vegetable proteins: only the food category 'meat imitates' was used in the exposure assessment. Fish analogues based on vegetable proteins are not included in the FoodEx nomenclature and therefore were not included in the exposure assessment;
- 14.1.4 Flavoured drinks, excluding chocolate milk; malt products: consumption of chocolate milk-based flavoured drinks was excluded from the assessment.

Overall, 10 food categories were not taken into account in the exposure assessment because they or their specific restrictions/exceptions are not referenced in the EFSA Comprehensive Database. This may result in an underestimation of the exposure. Three food categories were included in the exposure assessment without considering the restrictions/exceptions as set in Annex II to Regulation (EC) No 1333/2008, as amended. This may result in an overestimation of the exposure. For the remaining food categories, the refinements considering the restrictions/exceptions as set in Annex II to Regulation (EC) No 1333/2008, as amended, were applied.

2.2. Methodologies

Dietary exposure to Quinoline Yellow (E 104) from its use as a food colour was estimated using the approach adopted by the Panel at its 52nd plenary meeting[20]. This approach is to be followed to assess the exposure as part of the safety assessment of food additives under re-evaluation with the use of the food consumption data available within the EFSA Comprehensive Database, as presented in Table 3, and with the limitations described below.

Dietary exposure was estimated based on individual food consumption over the total survey period, excluding surveys with only one day per subject, which are considered to be inadequate to assess chronic dietary exposure, as suggested by the EFSA Working group on Food Consumption and Exposure (EFSA, 2011a).

The exposure to Quinoline Yellow (E 104) was calculated for the following population groups: toddlers, children, adolescents, adults and the elderly. For the present assessment, food consumption data were available from 26 different dietary surveys carried out in 17 different European countries, as shown in Table 3.

Table 3: Population groups considered for the exposure estimates of Quinoline Yellow (E 104)

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

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

Consumption records were codified according to the FoodEx food classification system (EFSA, 2011b). Nomenclature from the FoodEx classification system has been linked to the 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 either MPLs reported in Table 2 or values reported in Appendix C per food category with their corresponding consumption amount per kilogram body weight 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 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 were calculated per survey for the total population (including non-consumers) and per population group.

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

High-level exposure (95th percentile) was calculated only for population groups in which the sample size was sufficiently large (EFSA, 2011a). Therefore, in the present estimate, high-level (95th percentile) exposure figures for toddlers from Belgium, Italy and Spain were not reported.

The concentration values were considered for calculating dietary exposure to Quinoline Yellow (E 104) from its use as a food additive based on (1) MPLs set out in the EU legislation (the *regulatory maximum level exposure assessment* scenario); and (2) analytical data (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 set out in Annex II to Regulation (EC) No 1333/2008, as amended, and listed in Table 2.

The exposure estimates derived following this scenario should be considered as the most conservative estimates, as it assumes that the consumer will be continuously (over a lifetime) exposed to Quinoline Yellow (E 104) present in food at the MPLs. It should be noted, however, that, as described in Section 2.1.3.2, some food items could not be taken into account in the present exposure assessment for all scenarios. This should nevertheless represent a minor underestimation of dietary exposure.

2.2.2. Refined exposure assessment scenario

The refined exposure assessment scenario is based on reported use levels from industry and analytical results submitted to EFSA by Member States. This exposure scenario can consider only food categories for which these data are available.

Based on the available datasets, two estimates based on different model populations are calculated:

- The brand-loyal consumer scenario: it is assumed that a consumer experiences long-term exposure to the food additive at the maximum reported use/analytical levels for one food category and at the average for the remaining food categories. This exposure estimate is calculated as follows:
  - food consumption is combined 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;
  - the mean of the typical reported use levels or the mean of analytical results is used for the remaining food categories.
- The non-brand-loyal consumer scenario: it is assumed that a consumer experiences long-term exposure to the food additive at the mean reported use/analytical levels in all relevant foods. 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). To handle 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' (FAO and WHO, 2009) and the EFSA scientific report 'Management of left-censored data in dietary exposure assessment of chemical substances' (EFSA, 2010b) is used. For analytical results below LOD or LOQ, the mean middle-bound value (< LOD/LOQ = half of the LOD/LOQ) is used for each food category. 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 Quinoline Yellow (E 104) both refined exposure assessment scenarios were performed as described above. Analytical levels were considered the most reliable, owing to the wide range of data submitted, and as such giving better representativeness throughout the EU Member States. Appendix C summarises the analytical levels of Quin**o**line Yellow (E 104) used in the refined exposure assessment scenarios.

Food categories for which no or inadequate analytical data (all analytical data below LOD/LOQ for a food category) were available, were not considered in the refined exposure assessment scenarios. These food categories included flavoured fermented milk products (FCS food category 1.4), seasonings and condiments (FCS food category 12.2.2), mustard (FCS food category 12.4), protein products (FCS food category 12.9), dietary foods for special medical purposes (FCS food category 13.2), dietary foods for weight control diets (FCS 13.3) and spirits (FCS food category 14.2.6). This may have resulted in an underestimation of the exposure.

3. Assessment

3.1. Exposure to Quinoline Yellow (E 104) from its use as a food additive

Table 4 summarises the estimated exposure to Quinoline Yellow (E 104) 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 exposure to Quinoline Yellow (E 104) from its use as a food additive using the regulatory maximum level (MPL) exposure assessment scenario and refined exposure scenarios, in five population groups (minimum–maximum 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 (MPL) exposure assessment scenario					
Mean	0.03–0.23	0.02–0.18	0.004–0.11	0.01–0.08	0.004–0.03
High level (95th percentile)	0.14–0.40	0.07–0.40	0.02–0.24	0.04–0.27	0.02–0.11
Refined estimated exposure scenario					
Brand-loyal scenario					
Mean	0.003–0.15	0.01–0.11	0.004–0.08	0.005–0.06	0.001–0.01
High level (95th percentile)	0.02–0.22	0.05–0.29	0.02–0.18	0.03–0.17	0.01–0.05
Non-brand-loyal scenario					
Mean	0.001–0.03	0.002–0.02	0.001–0.02	0.001–0.01	0.0002–0.003
High level (95th percentile)	0.004–0.04	0.01–0.05	0.003–0.03	0.004–0.03	0.001–0.01

3.2. Main food categories contributing to exposure to Quinoline Yellow (E 104)

The main food categories contributing to total mean exposure to Quinoline Yellow (E 104) (> 5 % of total exposure) calculated for the *regulatory maximum level exposure assessment* scenario and the brand-loyal and non-brand-loyal refined scenarios, as well as the number of surveys in which each food category contributed >5% to the total mean exposure to Quinoline Yellow (E 104), are shown in Tables 5, 6 and 7, respectively.

The contribution of individual food categories to the total mean exposure to Quinoline Yellow (E 104) varies between age groups owing to different consumption patterns.

When considering the *regulatory maximum level exposure assessment* scenario (Table 5), flavoured drinks and flavoured fermented milk products were the main contributors for toddlers and children, whereas flavoured drinks and sauces were the main contributors for adolescents. In adults and the elderly, besides flavoured drinks, alcoholic beverages were also an important contributor to the total mean exposure to Quinoline Yellow (E 104).

For the brand-loyal scenario, the food categories that, at the individual level, had the highest contribution to the total individual mean exposure to Quinoline Yellow (E 104) were identified for each age group. Flavoured drinks were the main contributors for all age groups. Other important contributors to the total individual mean exposure to Quinoline Yellow (E 104) were desserts for toddlers, other confectionery for children and sauces for adolescents, adults and the elderly (Table 6).

In the non-brand-loyal scenario (Table 7), the contribution of the food categories was almost identical to that in the brand-loyal scenario, except that, in children, sauces were the second main contributor to total mean exposure to Quinoline Yellow (E104) compared with other confectionery in the brand-loyal scenario.

Table 5: Main food categories contributing to exposure to Quinoline Yellow (E 104) using MPLs (> 5 % to the total mean exposure) and number of surveys in which each food category is a contributor

FCS category no	Food category	Minimum and maximum percentage contribution of food categories to total dietary exposure across dietary surveys (number of surveys) [(a)]				
		Toddlers	Children	Adolescents	Adults	The elderly
1.4	Flavoured fermented milk products including heat treated products	16.3–86.2 (7)	9.8–48.8 (13)	6.0–29.1 (10)	5.8–21.8 (11)	8.6–28.0 (6)
5.2	Other confectionery including breath freshening microsweets	6.0–11.2 (3)	5.2–24.1 (12)	5.2–14.0 (8)	5.8–10.6 (3)	–
9.3	Fish roe	–	10.2 (1)	16.1 (1)	7.8 (1)	5.4 (1)
12.2	Herbs, spices, seasonings	5.4–5.8 (2)	–	6.5 (1)	9.2 (1)	16.0 (1)
12.6	Sauces	5.7–7.6 (4)	5.7–27.5 (8)	5.1–35.0 (9)	9.1–28.2 (9)	18.4–37.9 (3)
14.1.4	Flavoured drinks	7.1–66.5 (6)	21.4–86.4 (15)	26.1–74.5 (12)	15.2–81.1 (15)	6.2–74.6 (7)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	–	–	7.2–19.0 (3)	5.3–59.7 (15)	14.6–65.0 (7)
16	Desserts excluding products covered in categories 1, 3 and 4	16.6–20.2 (2)	6.6–19.1 (6)	5.9–13.3 (4)	6.3–7.3 (2)	6.0–12.9 (3)

(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 exposure to Quinoline Yellow (E 104) using the brand-loyal refined exposure scenario (> 5 % to the total mean exposure) and number of surveys in which each food category is a contributor

FCS category no	Food category	Minimum and maximum percentage contribution of food categories to total dietary exposure across dietary surveys (number of surveys) [(a)]				
		Toddlers	Children	Adolescents	Adults	The elderly
5.2	Other confectionery including breath freshening microsweets	7.9–26.0 (5)	5.6–40.0 (11)	5.8–15.4 (5)	6.6–25.2 (3)	6.1–22.0 (3)
9.3	Fish roe	–	–	6.7 (1)	–	5.2 (1)
12.6	Sauces	7.0–14.6 (4)	5.4–29.8 (5)	5.3–31.5 (7)	6.1–44.5 (9)	5.7–54.6 (5)
14.1.4	Flavoured drinks	51.9–90.8 (6)	31.6–94.2 (15)	45.1–97.2 (12)	43.9–99.0 (15)	24.0–96.9 (7)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	–	–	–	13.4–36.3 (3)	5.1–10.3 (3)
16	Desserts excluding products covered in categories 1, 3 and 4	29.0–83.5 (2)	5.6–19.5 (6)	6.7–10.7 (4)	9.2–9.5 (2)	8.7–26.2 (3)
17	Food supplements	–	–	–	–	8.5–17.6 (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 exposure to Quinoline Yellow (E 104) following the non-brand-loyal exposure scenario (> 5 % to the total mean exposure) and number of surveys in which each food category is a contributor

FCS category no	Food category	Minimum and maximum percentage contribution of food categories to total dietary exposure across dietary surveys (number of surveys) [(a)]				
		Toddlers	Children	Adolescents	Adults	The elderly
5.2	Other confectionery including breath freshening microsweets	8.9–33.6 (6)	6.9–48.2 (14)	5.7–20.8 (9)	7.6–24.3 (5)	7.4–21.3 (3)
5.3	Chewing gum	7.1 (1)	–	–	–	–
9.3	Fish roe	–	7.6 (1)	11.9 (1)	7.3 (1)	5.1–12.4 (2)
12.6	Sauces	17.4–32.3 (5)	7.2–51.3 (12)	5.7–53.9 (11)	8.3–64.8 (14)	8.0–69.0 (7)
14.1.4	Flavoured drinks	35.7–79.8 (6)	17.5–88.2 (15)	25.4–89.9 (12)	25.1–95.7 (15)	12.7–91.9 (7)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	–	–	–	8.4–32.6 (5)	8.6–18.3 (3)
16	Desserts excluding products covered in categories 1, 3 and 4	5.8–58.8 (4)	5.6–20.2 (8)	6.1–13.5 (4)	5.2–10.5 (3)	5.6–16.8 (2)
17	Food supplements	–	–	–	5.2–7.3 (2)	18.8–27.9 (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.

3.3. Uncertainty analysis

According to the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2006), the sources of uncertainties have been considered. These have already been discussed in the sections above and are summarised in Table 8.

Table 8: Qualitative evaluation of influence of uncertainties

Sources of uncertainties	Direction [(a)]
Consumption data: different methodologies/representativeness/under reporting/misreporting/no portion size standard	+/–
Use of food consumption surveys of few days to estimate long-term (chronic) exposure	+
Correspondence of reported analytical levels to the food items in the EFSA Comprehensive Food Consumption Database: uncertainties on the precise types of food the levels refer to	+/–
Use of MPLs in exposure assessment	+
Brand-loyal exposure model: exposure calculations based on the maximum reported analytical levels for one food category and mean reported use/analytical values for the remaining food categories	+/–
Non-brand-loyal exposure model: exposure calculations based on the mean reported analytical levels	+/–
Concentration (usage or analytical) data: no or inadequate information on occurrence available	–
Uncertainty in possible national differences in use levels of Quinoline Yellow (E104) in food categories; dataset not fully representative of foods on the EU market	+/–

(a): +, uncertainty with the 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 Quinoline Yellow (E 104) and concluded that overall uncertainty could lead to an overestimation of the calculated exposure estimates in MPL scenario.

3.4. Discussion

EFSA has performed an updated exposure assessment of Quinoline Yellow (E 104) used as a food additive, taking into consideration its MPLs laid down in Annex II to Regulation (EC) No 1333/2008, amended by the European Commission as regards the conditions of use (Commission Regulation (EU) No 232/2012), as well as submitted information on its reported use provided by industry and analytical data reported by the Member States.

Before 2014, EFSA has used the maximum concentration value (maximum reported usage/analytical level) available for each authorised food category for the performance of a refined exposure assessment. However, given the extensive range of usage/analytical data that has been made available through the most recent calls, it was considered that these data should be used in additional refined scenarios of the exposure assessment approach intended to provide more realistic exposure estimates. An approach addressing this was adopted by the ANS Panel at its 52nd plenary meeting[21] and is to be followed for assessing the exposure as part of the safety assessment of food additives under re-evaluation, in addition to the MPL scenario. Following this approach, EFSA calculates the refined exposure scenarios based on two assumptions: a brand-loyal consumer scenario, in which it is assumed that a consumer experiences long-term exposure to the food additive at the maximum reported usage/analytical levels for one food category and at the mean reported usage/analytical levels for the remaining food categories; and a non-brand-loyal consumer scenario, in which it is assumed that a consumer experiences long-term exposure to the food additive at the mean reported usage/analytical levels in all foods.

Overall, the regulatory maximum level exposure assessment scenario is considered to be the most conservative, as it assumes that all authorised processed foods and beverages contain the food additive at the MPLs. On the other hand, the refined exposure assessment approach is considered to be a more

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

realistic scenario, as it is based on the range of usage/analytical data provided by industry and Member States. This scenario assumes that the processed foods and beverages contain the food additive at the mean concentration level for all food categories (non-brand-loyal consumer scenario) except for one food category (the main contributing food category per individual), where it assumes that it contains the food additive at the maximum concentration level (brand-loyal consumer scenario). For this exposure assessment scenario, food categories with no or inadequate reported use/analytical levels are not considered in the exposure assessment.

The results of the present exposure assessment for Quinoline Yellow (E 104) following the *regulatory maximum level exposure assessment* (MPL) scenario are estimated to be much lower (by a factor of around 10 to 20 depending on the age group) than in the evaluation carried out in 2009 (EFSA ANS Panel, 2009) at both the mean and the 95th percentile exposure levels. However, the estimates cannot be accurately compared owing to the amendment of Annex II to Regulation (EC) No 1333/2008 in 2012. Following the conclusions of the EFSA Opinion on Quinoline Yellow (E 104) adopted in 2009 by the ANS Panel (EFSA ANS Panel, 2009), Annex II to Regulation (EC) No 1333/2008 was amended as regards the conditions of use and the use levels for Sunset Yellow FCF (E 110), Quinoline Yellow (E 104) and Ponceau 4R (E 124) (Commission Regulation (EU) No 232/2012[22]). For Quinoline Yellow (E 104), MPLs, when not withdrawn (n = 14), were decreased by a factor of 1.1 to 50, depending on the food category, applicable from 1 June 2013. The differences in the outcomes between the current and previous exposure estimates for Quinoline Yellow (E 104) using the MPL scenario are therefore likely to be the result of the lower MPLs in the present assessment, but also a result of the availability of more detailed consumption data covering a range of European countries. Indeed, some of the child consumption surveys currently included in the EFSA Comprehensive Database were also used in the opinion of the ANS Panel on Quinoline Yellow (E 104) in 2009, but the food categories used in the previous assessment were broader with respect to those available in FoodEx which was used in the present assessment. In the current assessment, individual food consumption data were used to estimate dietary exposure, whereas, in the 2009 ANS opinion, only summary statistics were available. Moreover, for adults, only UK consumption data were available, retrieved from a UNESDA report (Tennant, 2006).

For the refined exposure assessment, the differences between the current and the previous assessment are the result of the newly available information on reported levels, an updated exposure scenario, new food consumption data and a refined selection of food items within the FoodEx nomenclature. EFSA noted that updated information on the actual use levels of Quinoline Yellow (E 104) in foods and beverages made available by the industry covered only a few of the food categories in which this food additive is authorised. The majority of analytical data on Quinoline Yellow (E 104) in foods provided by Member States were collected before June 2013 and therefore may not be up to date as regards the conditions of use (Commission Regulation (EU) No 232/2012), as mentioned above. However, in the absence of more recent data, data collected before 2013 were also used for the refined exposure assessment scenario, provided that the values were below the currently authorised MPLs of use of Quinoline Yellow (E 104). It was noted that for many food categories in which the use of Quinoline Yellow (E 104) as a food additive is authorised, neither usage data nor quantified analytical data were reported. For the refined exposure estimates, when for a certain food category both usage and analytical levels were available, analytical levels were considered the most reliable, owing to the wide range of data submitted, thus being more representative of EU Member States. The exposure estimates were considerably lower at the mean and high exposure levels, for both children and adults, in the current assessment compared with the 2009 assessment. However, a reliable comparison with the previous assessment is not possible owing to the different approaches taken. In the 2009 assessment, the exposure calculation was based on maximum usage levels available for all food categories authorised for use of Quinoline Yellow (E 104) at that time, whereas in the current assessment, besides

[22] Commission Regulation (EU) No 232/2012 of 16 March 2012 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the conditions of use and the use levels for Quinoline Yellow (E 104), Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124). OJ L 78, 17.03.2012, p. 12.

maximum analytical levels, mean analytical levels were also used and the food categories for which no analytical value was available were not included in the assessment.

For the adult population, the main contributing food categories under the MPL scenario were flavoured drinks and alcoholic beverages. Both food categories were also the most important contributors in the previous assessment (EFSA ANS Panel, 2009). In children, flavoured drinks and flavoured fermented milk products were important contributors, which is in line with the 2009 assessment. Regarding exposure estimates based on the two refined exposure scenarios, besides flavoured drinks, the most important contributors were sauces in adults and adolescents, desserts in toddlers and other confectionery in children.

Data considered for the current refined exposure assessment did not cover all food categories in which Quinoline Yellow (E 104) is authorised. Food categories for which no or inadequate use/analytical levels were available were not considered. Therefore, it should be noted that, if Quinoline Yellow (E 104) is nevertheless used in these food categories, the calculated refined exposure assessment might result in an underestimation of the exposure. This is particularly true for the fermented milk products food category, which was a very important contributor to total dietary exposure to Quinoline Yellow (E 104) in toddlers and children under the MPL scenario. It was observed that quantified analytical levels of Quinoline Yellow (E 104) were available for six food categories (other creams, fish roe, sauces, aromatised wine-product cocktails, other alcoholic drinks and desserts), whereas no use levels for these food categories were reported by industry. The FoodEx food classification system used in the Comprehensive Database provides very detailed information on the consumption of food items. However, it was not always possible to find an appropriate link between the food categories used in the Comprehensive Database and those listed in the food additive legislation, in particular with respect to the restrictions/exceptions. In cases of very particular restrictions/exceptions, for example 'only *mostarda di frutta*', it was assumed that the foods were rarely consumed and thus minor contributors to the total mean exposure to Quinoline Yellow (E 104). As the FoodEx classification system does not contain such a detailed classification of foodstuffs, the concentration value would not be assigned to the entire food category; therefore, it could not be included in the calculation. This approach might have led to an underestimation of dietary exposure. However, given a minor consumption of food categories which could not be included, the impact on the Quinoline Yellow (E 104) exposure estimate is likely to be negligible. In other cases, when different MPLs of more than one food sub-categories within the same food category applied, the highest MPL/analytical result was assigned to whole category when it was not possible to differentiate specific restrictions/exceptions. This approach may have resulted in an overestimation of the exposure in all three scenarios.

Toddlers and children were the population groups in which the highest exposure levels were observed for all three exposure scenarios considered. This is likely due to a higher amount of food consumed in relation to their body weight. Considering both the MPL and refined exposure scenarios, the estimated mean and 95th percentile of total dietary exposure to Quinoline Yellow (E 104) were below the ADI of 0.5 mg/kg bw/day for all age groups.

Overall, flavoured drinks were estimated to be very important contributors to the total exposure to Quinoline Yellow (E 104) under all three scenarios in all age groups. The FoodEx classification system includes several products within this food category, but it was assumed to be unlikely that Quinoline Yellow (E 104) is used in all types of soft drinks based on the large number of analytical data on flavoured drinks ($n \approx 1\,000$) received where values were quantified in only 6 % of the dataset; therefore, the exposure was likely to be overestimated for this food category, particularly in the brand-loyal consumer scenario, in which the highest reported level was used. The results indicated that flavoured fermented milk products are very important contributors to total dietary exposure to Quinoline Yellow (E 104) in toddlers and children under the MPL scenario. However, given that no usage levels or quantified analytical results were reported for this food category, it may be the case that Quinoline Yellow (E 104) is rarely used in flavoured fermented milk products. EFSA therefore considered that it is likely that, in such a case, the exposure estimates based on MPL scenario presented in this statement may overestimate a true exposure.

4. Conclusions

Following the conclusions of the EFSA Opinion on Quinoline Yellow (E 104) adopted in 2009 by the ANS Panel (EFSA ANS Panel, 2009), Annex II to Regulation (EC) No 1333/2008 was amended as regards the conditions of use and the use levels (Commission Regulation (EU) No 232/2012). For Quinoline Yellow (E 104), MPLs, when not withdrawn (n = 14), were decreased by a factor of 1.1 to 50, depending on the food category, applicable from 1 June 2013 onwards.

The current exposure estimates for Quinoline Yellow (E 104) provide an update of the exposure assessment performed in 2009 (EFSA ANS Panel, 2009).

EFSA concluded that using MPLs for calculations, both mean and high-level (95th percentile) exposure estimates were below the ADI for all population groups. Considering the refined exposure scenarios based on reported analytical levels, and assuming that Quinoline Yellow (E 104) is not used in food categories for which no data was provided, the mean and high-level exposure estimates of Quinoline Yellow (E 104) were below the ADI for all population groups.

In comparison with the previous assessment carried out in 2009, the current exposure estimates based on the MPL scenario and refined scenarios, for both children and adults, were lower. The estimates should be compared with caution owing to the different approaches taken to assess the exposure. The differences in exposure estimates are mainly the result of lower MPLs laid down in 2012 on which the current MPL scenario exposure estimate was based; new information on reported analytical levels, an updated exposure scenario incorporating assumptions about brand-loyalty, new food consumption data covering a wider number of countries. The refined selection of food items within the FoodEx nomenclature also contributed to a lower exposure estimates for all population groups.

EFSA noted that, for 13 out of the 28 food categories in which Quinoline Yellow (E 104) is authorised for use as a food additive, neither usage data nor quantified analytical data were reported.

DOCUMENTATION PROVIDED TO EFSA

1. FoodDrinkEurope (FDE). Data on use levels of Quinoline Yellow (E 104). Submitted on 29 November 2013.

2. International Chewing Gum Association (ICGA). Data on use levels of Quinoline Yellow (E 104). Submitted on 29 November 2013.

3. Association of the European Self-Medication Industry (AESGP). Data on use levels of Quinoline Yellow (E 104). Submitted on 29 November 2013.

4. 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).

REFERENCES

EFSA (European Food Safety Authority), 2006. Opinion of the Scientific Committee related to uncertainties in dietary exposure assessment. The EFSA Journal 2006, 438, 1–54.

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), 2009. Scientific Opinion on the re-evaluation of Quinoline Yellow (E 104) as a food additive. EFSA Journal 2009;7(11):1329, 40 pp. doi:10.2903/j.efsa.2009.1329

EFSA (European Food Safety Authority), 2010a. Standard sample description for food and feed. EFSA Journal 2010;8(1):1457, 54 pp. doi:10.2903/j.efsa.2010.1457

EFSA (European Food Safety Authority), 2010b. Management of left-censored data in dietary exposure assessment of chemical substances. EFSA Journal 2010;8(3):1557, 96 pp. doi:10.2903/j.efsa.2010.1557

EFSA (European Food Safety Authority), 2011a. Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. EFSA Journal 2011;9(3):2097, 34 pp. doi:10.2903/j.efsa.2011.2097

EFSA (European Food Safety Authority), 2011b. Evaluation of the FoodEx, the food classification system applied to the development of the EFSA Comprehensive European Food Consumption Database. EFSA Journal 2011;9(3):1970, 27 pp. doi:10.2903/j.efsa.2011.1970

FAO (Food and Agriculture Organization) and WHO (World Health Organization), 2009. Principles and methods for the risk assessment of chemicals in food. Chapter 2: risk assessment and its role in risk analysis. International Programme on Chemical Safety, Environmental Health Criteria 240. Available online: http://whqlibdoc.who.int/ehc/WHO_EHC_240_5_eng_Chapter2.pdf

Huybrechts I, Sioen I, Boon PE, De Neve M, Amiano P, Arganini C, Bower E, Busk L, Christensen T, Hilbig A, Hirvonen T, Kafatos A, Koulouridaki S, Lafay L, Liukkonen K-H, Papoutsou S, Ribas-Barba L, Ruprich J, Rehurkova I, Mathilde K, Serra-Majem L, Turrini A, Verger E, Westerlund A, Tornaritis M, van Klaveren JD and De Henauw S, 2010. Long-term dietary exposure to different food colours in young children living in different European countries. Scientific report submitted to EFSA. May 2010. 70 pp. Available online: http://www.efsa.europa.eu/en/search/doc/53e.pdf

JECFA (WHO/FAO Joint Expert Committee on Food Additives), 1975. 18th report Toxicological evaluation of some food colours, enzymes, flavour enhancers, thickening agents, and certain other food additives. WHO Food Additives Series, 6.

JECFA (WHO/FAO Joint Expert Committee on Food Additives), 1978. 22nd report Summary of toxicological data of certain food additives and contaminants. WHO Food Additives Series, 13.

JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1984. 28th report. Toxicological evaluation of certain food additives and contaminants. WHO Food Additives Series, No. 19.

JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2011. 74th report. Evaluation of certain food additives and contaminants. WHO Technical Report Series, No. 966.

SCF (Scientific Committee for Food), 1984. Food – science and techniques. Reports of the Scientific Committee for Food (fourteenth series), opinion expressed in 1983. Commission of the European Communities, Luxembourg City, Luxembourg. Available online: http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_14.pdf

Tennant D, 2006. Screening of colour intakes from non-alcoholic beverages. Report prepared for the Union of European Beverages Associations (UNESDA). December 2006.

APPENDICES

Appendix A. Summary of the reported use levels (mg/kg or mg/l as appropriate) of Quinoline Yellow (E 104) provided by industry (only usage levels complying with the current MPLs were considered)

FCS category no	FCS food category	MPL	Restrictions/exceptions	Reported usage levels			
				Number of data	Typical mean	Highest maximum level	Information provided by
5.2	Other confectionery including breath freshening microsweets	30	Except candied fruit and vegetables	1	20	30	FDE
5.3	Chewing gum	30		1	20	30	FDE
6.6	Batters	50		1	32	32	FDE
14.1.4	Flavoured drinks	10	Excluding chocolate milk; malt products	11	5.1	10	FDE

Appendix B. Summary of analytical results (middle bound mg/kg or mg/l as appropriate) of Quinoline Yellow (E 104) provided by Member States (only analytical results complying with the current MPLs were considered)

FCS category no	FCS food category	MPL	n	%LC	Range		All data					Positive values					
					LOD	LOQ	Min	Median	Mean	P95 [(a)]	Max	n	Min	Median	Mean	P95 [(a)]	Max
1.4	Flavoured fermented milk products	10	13	100	0.0–8.0	0.01–8.0	0.00	0.10	0.76	–	4.00	–	–	–	–	–	–
1.6.3	Other creams	10	6	17	0.04–0.2	0.1–0.5	0.25	4.30	4.54	–	9.70	5	1.00	4.40	5.40	–	9.70
4.2.4.1	Fruit and vegetable preparations, excluding compote	30	22	100	20–20	60–60	10.0	10.0	10.0	–	10.0	–	–	–	–	–	–
5.2	Other confectionery - only candied fruit and vegetables	30	24	83	0.04–20	0.1–60	0.05	1.15	4.20	–	10.0	4	0.10	0.70	0.70	–	1.30
	Other confectionery -except candied fruit and vegetables	30	816	69	0.02–20	0.07–60	0.03	2.50	5.92	19.5	30.0	257	0.10	10.0	10.8	27.1	30.0
5.3	Chewing gum	30	22	55	0.04–20	0.1–60	0.20	7.00	7.85	–	28.4	10	5.00	10.9	12.7	–	28.4
9.3	Fish roe	200	6	33	0.04–0.2	0.1–2.0	1.00	14.5	19.8	–	64.7	4	11.0	20.5	29.2	–	64.7
12.2.2	Seasonings and condiments	10	31	100	0.2–20	0.5–60	0.20	2.50	4.44	–	10.0	–	–	–	–	–	–
12.4	Mustard	10	7	100	0.2–0.3	0.5–5.0	0.25	1.57	2.50	–	2.50	–	–	–	–	–	–
12.6	Sauces	20	62	92	0.03–20	0.05–60	0.01	2.50	5.40	10.0	16.0	5	5.00	5.00	9.40	–	16.0
13.2	Dietary foods for special medical purposes	10	15	100	0.02–8.0	0.03–8.0	0.01	0.20	0.39	–	4.00	–	–	–	–	–	–
14.1.4	Flavoured drinks	10	1051	94	0.0–15	0.02–15	0.00	0.25	1.35	4.00	10.0	65	0.10	4.00	4.00	–	10.0
14.2.3	Cider and perry	25	188	99	0.03–20	0.05–60	0.01	0.50	4.56	10.0	10.0	2	1.20	3.60	3.60	–	6.00
14.2.7.3	Aromatised wine-product cocktails	50	42	98	0.03–20	0.05–60	0.01	0.20	2.66	–	10.0	1	–	–	–	–	8.70

FCS category no	FCS food category	MPL	n	%LC	Range		All data					Positive values					
					LOD	LOQ	Min	Median	Mean	P95 [(a)]	Max	n	Min	Median	Mean	P95 [(a)]	Max
14.2.8	Other alcoholic drinks	180	36	64	0.04–20	0.1–60	0.25	2.64	8.54	–	66.0	13	0.82	1.27	14.1	–	66.0
16	Desserts	10	25	80	0.03–4.0	0.05–12	0.01	0.40	1.38	–	9.10	5	1.40	2.60	4.10	–	9.10
17	Food supplements	10/35	47	85	0.09–20	0.5–60	0.20	10.0	6.8	–	26.0	7	1.97	15.0	14.2	–	26.0

(a): The 95th percentile obtained on occurrence data with fewer than 60 analytical results may not be statistically robust (EFSA, 2011a) and therefore are not reported in the table.
%LC, percentage of left-censored data; Max, maximum; Min, minimum; n, number of data; P95, 95th percentile.

Appendix C. Concentration levels of Quinoline Yellow (E 104) used in the refined exposure scenarios (mg/kg or ml/kg as appropriate)

FCS category no	FCS food category	MPL	Concentration levels used in the refined exposure assessment		Data source/comments
			Mean	Maximum	
1.4	Flavoured fermented milk products, including heat-treated products	10	–	–	No adequate data available
1.6.3	Other creams	10	–	–	Not taken into account (no corresponding FoodEx code)
1.7.3	Edible cheese rind	10	–	–	Not taken into account (no corresponding FoodEx code)
4.2.4.1	Fruit and vegetable preparations excluding compote - only *mostarda di frutta*	30	–	–	Not taken into account (no corresponding FoodEx code)
5.2	Other confectionery including breath freshening microsweets - except candied fruit and vegetables	30	5.92	30.0	Analytical data
5.2	Other confectionery including breath freshening microsweets - only candied fruit and vegetables	30	4.20	10.0	Analytical data
5.2	Other confectionery including breath freshening microsweets - only traditional sugar coated nut- or cocoa-based confectionery of almond shape or host shape, typically longer than 2 cm and typically consumed at celebratory occasions, i.e. weddings, communion, etc.	300	–	–	Not taken into account (no corresponding FoodEx code)
5.3	Chewing gum	30	7.85	28.4	Analytical data
5.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4 - only decorations, coatings and sauces, except fillings	50	–	–	Not taken into account (no corresponding FoodEx code)
5.4	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)
6.6	Batters	50	–	–	Not taken into account (no corresponding FoodEx code)
8.3.3	Casings and coatings and decorations for meat - only decorations and coatings except edible external coating of *pasturmas*	50	–	–	Not taken into account (no corresponding FoodEx code)
8.3.3	Casings and coatings and decorations for meat - only edible casings	10	–	–	Not taken into account (no corresponding FoodEx code)
9.3	Fish roe	200	19.8	64.7	Analytical data
12.2.2	Seasonings and condiments	10	–	–	No adequate data available
12.4	Mustard	10	–	–	No adequate data available

FCS category no	FCS food category	MPL	Concentration levels used in the refined exposure assessment		Data source/comments
			Mean	Maximum	
12.6	Sauces	20	5.40	16.0	Analytical data
12.9	Protein products, excluding products covered in category 1.8	10	–	–	No data available
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	10	–	–	No adequate data available
13.3	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)	10	–	–	No data available
14.1.4	Flavoured drinks	10	1.35	10.0	Analytical data
14.2.3	Cider and perry	25	4.56	10.0	Analytical data
14.2.4	Fruit wine and made wine	20	–	–	Not taken into account (no corresponding FoodEx code)
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	180	–	–	No data available
14.2.7.1	Aromatised wines	50	–	–	No data available
14.2.7.2	Aromatised wine-based drinks	50	–	–	Not taken into account (no corresponding FoodEx code)
14.2.7.3	Aromatised wine-product cocktails	50	–	–	Not taken into account (no corresponding FoodEx code)
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol	180	8.54	66.0	Analytical data
16	Desserts excluding products covered in category 1, 3 and 4	10	1.38	9.10	Analytical data
17.1/17.2/17.3	Food supplements	35/10/10	6.8	26.0	Analytical data

Appendix D. Summary of total estimated exposure of Quinoline Yellow (E 104) from its use as a food additive for the MPL scenario and refined exposure scenarios per population group and survey: mean and high level (95th percentile exposure) (mg/kg bw/day)

	Number of subjects	MPL scenario		Brand-loyal scenario		Non-brand-loyal scenario	
		Mean	High level	Mean	High level	Mean	High level
Toddlers							
Belgium (Regional_Flanders)	36	0.23	–[(a)]	0.15	–[(a)]	0.03	–[(a)]
Bulgaria (NUTRICHILD)	428	0.03	0.14	0.02	0.13	0.003	0.02
Finland (DIPP)	497	0.05	0.20	0.01	0.02	0.001	0.004
Germany (DONALD_2006_2008)	261	0.04	0.16	0.02	0.10	0.004	0.02
Italy (INRAN_SCAI_2005_06)	36	0.03	–[(a)]	0.003	–[(a)]	0.001	–[(a)]
Spain (EnKid)	17	0.07	–[(a)]	0.02	–[(a)]	0.003	–[(a)]
The Netherlands (VCP_kids)	322	0.16	0.40	0.07	0.22	0.01	0.04
Children							
Belgium (Regional_Flanders)	625	0.17	0.40	0.09	0.29	0.02	0.04
Bulgaria (NUTRICHILD)	433	0.05	0.19	0.04	0.18	0.006	0.03
Czech Republic (SISP04)	389	0.08	0.24	0.05	0.21	0.009	0.03
Denmark (Danish_Dietary_Survey)	490	0.10	0.22	0.08	0.19	0.01	0.03
Finland (DIPP)	933	0.06	0.17	0.03	0.10	0.005	0.02
Finland (STRIP)	250	0.08	0.17	0.04	0.11	0.01	0.03
France (INCA2)	482	0.06	0.16	0.04	0.13	0.008	0.02
Germany (DONALD_2006_2008)	660	0.10	0.27	0.07	0.23	0.01	0.04
Greece (Regional_Crete)	839	0.02	0.08	0.01	0.05	0.002	0.01
Italy (INRAN_SCAI_2005_06)	193	0.02	0.07	0.01	0.05	0.002	0.01
Latvia (EFSA_TEST)	189	0.03	0.10	0.03	0.08	0.006	0.02
Spain (enKid)	156	0.06	0.18	0.03	0.09	0.006	0.02
Spain (NUT_INK05)	399	0.06	0.16	0.03	0.11	0.007	0.02
Sweden (NFA)	1473	0.18	0.37	0.11	0.27	0.02	0.05
The Netherlands (VCP_kids)	957	0.15	0.37	0.06	0.20	0.01	0.04
Adolescents							
Belgium (Diet_National_2004)	584	0.07	0.21	0.06	0.18	0.01	0.03
Cyprus (Childhealth)	303	0.004	0.02	0.004	0.02	0.001	0.003
Czech Republic (SISP04)	298	0.06	0.21	0.04	0.16	0.01	0.03
Denmark (Danish_Dietary_Survey)	479	0.08	0.18	0.07	0.18	0.01	0.03
France (INCA2)	973	0.03	0.10	0.02	0.08	0.004	0.01
Germany (National_Nutrition_Survey_II)	1011	0.05	0.14	0.03	0.10	0.01	0.02
Italy (INRAN_SCAI_2005_06)	247	0.02	0.07	0.01	0.06	0.002	0.01
Latvia (EFSA_TEST)	470	0.02	0.07	0.02	0.05	0.004	0.01
Spain (AESAN_FIAB)	86	0.02	0.09	0.01	0.06	0.002	0.01
Spain (enKid)	209	0.03	0.09	0.02	0.06	0.004	0.01
Spain (NUT_INK05)	651	0.04	0.12	0.03	0.09	0.01	0.02
Sweden (NFA)	1018	0.11	0.24	0.08	0.18	0.02	0.03
Adults							
Belgium (Diet_National_2004)	1304	0.06	0.19	0.04	0.14	0.01	0.03
Czech Republic (SISP04)	1666	0.02	0.10	0.01	0.06	0.002	0.01
Denmark (Danish_Dietary_Survey)	2822	0.04	0.13	0.03	0.10	0.004	0.02
Finland (FINDIET_2007)	1575	0.04	0.13	0.01	0.05	0.003	0.01
France (INCA2)	2276	0.03	0.10	0.01	0.05	0.003	0.01
Germany (National_Nutrition_Survey_II)	10419	0.03	0.11	0.02	0.07	0.01	0.02

	Number of subjects	MPL scenario		Brand-loyal scenario		Non-brand-loyal scenario	
		Mean	High level	Mean	High level	Mean	High level
Hungary (National_Repr_Surv)	1074	0.02	0.08	0.02	0.08	0.003	0.01
Ireland (NSIFCS)	958	0.05	0.18	0.02	0.08	0.01	0.02
Italy (INRAN_SCAI_2005_06)	2313	0.01	0.04	0.005	0.03	0.001	0.004
Latvia (EFSA_TEST)	1306	0.02	0.07	0.01	0.03	0.002	0.01
Spain (AESAN)	410	0.03	0.12	0.02	0.08	0.003	0.02
Spain (AESAN_FIAB)	981	0.02	0.08	0.01	0.06	0.002	0.02
Sweden (Riksmaten_1997_98)	1210	0.05	0.16	0.03	0.09	0.01	0.02
The Netherland (DNFCS_2003)	750	0.08	0.21	0.06	0.17	0.01	0.03
United Kingdom (NDNS)	1724	0.07	0.27	0.03	0.11	0.01	0.02
Elderly and very elderly							
Belgium (Diet_National_2004)	1230	0.03	0.10	0.01	0.05	0.003	0.01
Denmark (Danish_Dietary_Survey)	329	0.03	0.11	0.01	0.04	0.001	0.01
Finland (FINDIET_2007)	463	0.02	0.09	0.001	0.01	0.001	0.004
France (INCA2)	348	0.02	0.05	0.01	0.02	0.002	0.01
Germany (National_Nutrition_Survey_II)	2496	0.02	0.05	0.01	0.03	0.002	0.01
Hungary (National_Repr_Surv)	286	0.02	0.05	0.01	0.04	0.002	0.01
Italy (INRAN_SCAI_2005_06)	518	0.004	0.02	0.001	0.01	0.0002	0.001

(a): The 95th percentile estimates obtained on dietary surveys/population groups with less 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
FAO	Food and Agriculture Organization of the United Nations
EXPOCHI	Individual food consumption data and exposure assessment studies for children
FCS	Food Categorisation System (food nomenclature) presented in the Commission Regulation (EU) No 1129/2011
FDE	FoodDrinkEurope
FIP	Food Ingredients and Packaging
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
SCF	Scientific Committee for Food
UK	United Kingdom
UNESDA	Union of European Soft Drinks Associations
WHO	World Health Organization