STATEMENT OF EFSA

Refined exposure assessment for caramel colours (E 150a, c, d)[1]

European Food Safety Authority[2, 3]

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ABSTRACT

This EFSA statement is a refined exposure assessment of caramel colours (E 150a, E 150c and E 150d) taking into account additional information on its use in foods as consumed. The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) adopted a scientific opinion on the re-evaluation of caramel colours (E 150a, E 150b, E 150c, E 150d) used as food additives in 2011. In that opinion, the Panel concluded that the anticipated dietary exposure of child and adult populations may exceed the Acceptable Daily Intake (ADI) for caramel colours E 150a, E 150c and E 150d, but exposure estimates to E 150b were below the ADI. Following this conclusion, new data from industry were submitted to EFSA providing updated use levels of caramel colours in foods ready to be consumed. A refined exposure assessment was performed for caramel colours that were exceeding the ADI in ANS Panel opinion (EFSA, 2011a) i.e. E 150a, E 150c and E 150d and concluded that the anticipated dietary exposure are considerably lower than in the previous exposure assessment. However, toddlers and adults have a higher exposure to caramel colour E 150c and could still exceed the ADI of 100 mg/kg bw/day for this caramel colour. The estimated combined exposure to the four caramel colours (E 150a, E 150b, E 150c, E 150d) are considerably lower and the group ADI of 300 mg/kg bw/day is not exceeded for any population group in the current review.

KEY WORDS

Caramel colours, E 150a, E 150c, E 150d, exposure, EFSA Comprehensive European Food Consumption Database, food colours.

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SUMMARY

This EFSA statement is a refined exposure assessment of caramel colours (E 150a, E 150c and E 150d) taking into account additional information on its use in foods as consumed.

Caramel colours are colouring substances authorised as food additives in the European Union (EU) for use in a number of foods according to the Commission Regulation (EU) N° 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) N°1333/2008 of the European Parliament and of the Council establishing a Union list of food additives. The caramel colours are divided into four classes, Class I Plain caramel (E 150a), Class II Caustic sulphite caramel (E 150b), Class III Ammonia caramel (E 150c), and Class IV Sulphite ammonia caramel (E 150d), according to the reactants used in their manufacture. The four classes of caramel colours have been previously evaluated by the EU Scientific Committee for Food (SCF, 1975, 1984, 1989, 1997) and by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1970, 1972a, 1972b, 1978, 1986, 1987, 2001). The Nordic Council of Ministers has reviewed the caramel colours in a report which took into account the literature published on these substances up to the year 2000 (TemaNord, 2002).

In 2011, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) adopted a scientific opinion on the re-evaluation of caramel colours (E 150a, E 150b, E 150c, E 150d) as food additives. The ANS Panel established a group ADI of 300 mg/kg body weight/day for four caramel colours (E 150a, E 150b, E 150c, E 150d) and an individual ADI of 100 mg/kg bw/day for E 150c (Class III Ammonia Caramel) due to immunotoxicity of one of its constituent. The ANS Panel concluded that, based on the data available, it was possible that the use of caramel colours in foods may lead to exposures in excess of the Acceptable Daily Intakes (ADIs): caramel colours E 150a and E 150d may exceed the group ADI of 300 mg/kg bw/day and E 150c may exceed the individual ADI of 100 mg/kg bw/day. On the opposite, caramel colour E 150b exposure estimates were below the group ADI of 300 mg/kg bw/day. The ANS Panel further noted that depending on the caramel colours, the main contributors to children's anticipated exposures were non-alcoholic beverages and within this category, flavoured drinks, fine bakery wares and desserts, including flavoured milk products; for adults, the main contributors were non-alcoholic beverages, beer and cider and confectionary. The ANS Panel also noted that the anticipated combined dietary exposure of both children and adults to all four caramel colours exceeded the group ADI of 300 mg/kg bw/day at the 95th/97.5th percentile, while the ADI is also exceeded by the combined mean exposure for children. In the case of children, this exceedance applied to the upper end of the exposure range only.

In 2012, data on the actual uses of caramel colours in foods as consumed were submitted to EFSA by industry. The present review provides a refined exposure assessment for caramel colours E 150a, E 150c, E 150d, based on these new data and consumption data available in the EFSA Comprehensive European Food Consumption Database.

Given that the anticipated exposure to caramel colour E 150b was below the group ADI of 300 mg/kg bw/day established by the ANS Panel in 2011 (EFSA, 2011a), the present statement does not include a refined dietary exposure for caramel colour E 150b.

EFSA concluded that in Europe the mean dietary exposures to caramel colour E 150a for toddlers (12-35 months old), children (3-9 years old) and adolescents (10-17 years old) range from 11 to 45 mg/kg bw/day, 15 to 39 mg/kg bw/day and 6 to 24 mg/kg bw/day, respectively. For caramel colour E 150c, the same population group exposures range from 10 to 60 mg/kg bw/day, 20 to 56 mg/kg bw/day and 9 to 33 mg/kg bw/day at the mean. For caramel colour E 150d, the mean dietary exposures for toddlers, children and adolescents range from 11 to 86 mg/kg bw/day, 19 to 62 mg/kg bw/day and 8 to 44 mg/kg bw/day, respectively.

At the 95th percentile, caramel colour E 150a exposure estimates range from 32 to 79 mg/kg bw/day for toddlers, from 36 to 81 mg/kg bw/day for children and from 16 to 56 mg/kg bw/day for

adolescents. For caramel colour E 150c, the anticipated high level exposures for toddlers, children and adolescents range from 36 to 106 mg/kg bw/day, from 43 to 97 mg/kg bw/day and from 20 to 86 mg/kg bw/day, respectively. The anticipated high level exposures for caramel colour E 150d range from 38 to 127 mg/kg bw/day for toddlers, from 49 to 136 mg/kg bw/day for children and from 21 to 122 mg/kg bw/day for adolescents.

For adults (18-64 years old) and the elderly (≥ 65 years old), the anticipated dietary exposure for caramel colour E 150a gives a mean range through all European countries, of respectively 6 to 18 mg/kg bw/day and 4 to 12 mg/kg bw/day; and of 16 to 42 mg/kg bw/day and 13 to 32 mg/kg bw/day at the 95th percentile. For caramel colour E 150c, the mean ranges from 10 to 43 mg/kg bw/day for adults and from 6 to 30 mg/kg bw/day for the elderly, with the 95th percentiles ranging from 27 to 151 mg/kg bw/day and from 14 to 82 mg/kg bw/day. For caramel colour E 150d, the mean ranges from 9 to 36 mg/kg bw/day for adults and from 6 to 22 mg/kg bw/day for the elderly; the 95th percentiles range from 26 to 101 mg/kg bw/day for adults and from 19 to 60 mg/kg bw/day for the elderly.

On the basis of the above estimates, high levels of dietary exposure to caramel colour E 150c for toddlers and adults could exceed the ADI of 100 mg/kg bw/day, respectively in one and five countries.

The anticipated combined exposures to caramel colours E 150a, E 150b, E 150c and E 150d give a mean range through all European countries, of respectively 19 to 105 mg/kg bw/day, 31 to 83 mg/kg bw/day, 12 to 56 mg/kg bw/day, 15 to 57 mg/kg bw/day, 9 to 35 mg/kg bw/day respectively for toddlers, children, adolescents, adults and the elderly. At the high levels, the estimated combined exposures range from 73 to 158 mg/kg bw/day, 68 to 160 mg/kg bw/day, 28 to 144 mg/kg bw/day, 41 to 161 mg/kg bw/day, 24 to 87 mg/kg bw/day for the same population groups. Thus, the estimated combined exposure to all four caramel colours is below the group ADI of 300 mg/kg bw/day for all population groups both at the mean and at the high level of exposure.

The results of the current exposure assessment for caramel colours E 150a, E 150c and E 150d and combined exposure to the four caramel colours are considerably lower than those of the original opinion (EFSA, 2011a).

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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 yellow[4], sunset yellow[5], ponceau 4R[6]). 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) N° 1129/2012[7]) and of the EFSA Comprehensive food consumption database (FoodEx), had been finalised, by 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) N° 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) N° 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)

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

ASSESSMENT

1. Introduction

Caramel colours are colouring substances authorised as food additives in the EU. The caramel colours are divided into four classes, Class I Plain caramel (E 150a), Class II Caustic sulphite caramel (E 150b), Class III Ammonia caramel (E 150c), and Class IV Sulphite ammonia caramel (E 150d), according to the reactants used in their manufacture. The four classes of caramel colours have been previously evaluated by the EU Scientific Committee for Food (SCF, 1975, 1984, 1989, 1997) and by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1970, 1972a, 1972b, 1978, 1986, 1987, 2001). The Nordic Council of Ministers has reviewed the caramel colours in a report which took into account the literature published on these substances up to the year 2000 (TemaNord, 2002).

In 2011 the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) has re-evaluated caramel colours (E 150a, E 150b, E 150c and E 150d) as food additives (EFSA, 2011a). The safety in use of caramel colours was assessed on the basis of the uses and use levels authorised in the legislation[8] and the reported use levels, as provided by industry.

The ANS Panel established a group ADI of 300 mg/kg bw/day for four caramel colours (E 150a, E 150b, E 150c, E 150d) and within this group ADI, established an individual ADI of 100 mg/kg bw/day for caramel colour E 150c due to concern regarding the immunotoxicity of a constituent of this caramel colour (2-acetyl-4-tetrahydroxybutylimidazole (THI), found in E 150c only).

The ANS Panel noted that the anticipated dietary exposure of the adult population at the 97.5th percentile to caramel colour E 150a exceeds the group ADI of 300 mg/kg bw/day proposed for the caramel colours, with a 97.5th percentile exposure estimate of 429 mg/kg bw/day. Similarly, the anticipated dietary exposure of the adult population at the 97.5th percentile to caramel colour E 150d exceeds this group ADI (high level exposure estimate of 369 mg/kg bw/day). For children, the upper end of both the mean intake ranges and also the 95th/97.5th percentile intakes for caramel colour E 150a exceed the group ADI of 300 mg/kg bw/day (exposures range respectively from 77 to 427 mg/kg bw/day at the mean and from 180 to 882 mg/kg bw/day at the 95/97.5th percentile). Similarly, for children, the upper end of both the mean intake ranges and also the 95th/97.5th percentile intakes for caramel colour E 150d exceed the group ADI of 300 mg/kg bw/day (exposures range respectively from 23 to 506 mg/kg bw/day at the mean and from 130 to 1480 mg/kg bw/day at the 95/97.5th percentile).

The main contributors to the total anticipated exposure to caramel colour E 150a were non-alcoholic flavoured drinks both for adults and children. For children, fine bakery wares, desserts including flavoured milk products and sauces, seasoning and pickles were also main contributing food categories. For adults, beer and cider and soups were also main contributors. The two main contributors to the anticipated exposures of children and adults to caramel colour E 150d were soft drinks and confectionary.

8 Commission Regulation (EU) N° 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) N° 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives. OJ L 295, 12.11.2011, p. 1–177

Table 1: Overview of exceedance of group or individual ADI in previous exposure assessment of caramel colours (EFSA, 2011a)

Caramel colour	Children		Adults	
	Mean	High level	Mean	High level
E 150a	> group ADI	> group ADI	> group ADI	> group ADI
E 150b	< group ADI	< group ADI	< group ADI	< group ADI
E 150c	> individual ADI	> individual ADI	> individual ADI	> individual ADI
E 150d	> group ADI	> group ADI	> group ADI	> group ADI
Combined exposure	> group ADI	> group ADI	> group ADI	> group ADI

The anticipated dietary exposure to caramel colour E 150b for both adults and children was below the group ADI of 300 mg/kg bw/day: from 22 to 110 mg/kg bw/day for adults respectively at the mean and high level and between 9 to 35 mg/kg bw/day at the mean and 18 to 117 mg/kg bw/day at high level for children.

For caramel colour E 150c, the upper end of the mean intake range for children exceeds the individual ADI of 100 mg/kg bw/day established for this colour within the group ADI (estimated mean range between 22 and 302 mg/kg bw/day), while the 97.5th percentile anticipated dietary exposures of both the child and adult populations are above this ADI of 100 mg/kg bw/day (high level exposure respectively range from 108 to 757 mg/kg bw/day for children and estimated at 295 mg/kg bw/day for adults). The food groups contributing the most to the anticipated exposure for children were fine bakery wares, desserts and sauces. For adults, food groups contributing most were beer and cider and sauces, seasoning and pickles.

Anticipated combined dietary exposures of both adults and children to all caramel colours exceed the group ADI of 300 mg/kg bw/day at the 95th/97.5th percentile (respectively of 474 mg/kg bw/day for adults and between 225 and 1672 mg/kg bw/day for children), while the ADI is also exceeded by the combined mean intake for children. In the case of children, this exceedance applies to the upper end of the exposure range only (range from 84 to 698 mg/kg bw/day).

The aim of the present statement is to provide refined exposure assessments for the caramels colours E 150a, E 150c and E 150d, from their uses as food colouring substances, taking into consideration updated information provided by industry in June, September and October 2012 on use levels in foods ready to be consumed.

Given that the anticipated exposure to caramel colour E 150b was below the group ADI of 300 mg/kg bw/day established by the ANS Panel in 2011 (EFSA, 2011a), the present statement does not include a refined dietary exposure for caramel colour E 150b.

Information on the minor constituents of caramel colours (4-MEI, THI, and sulphur dioxide) was presented by the ANS Panel previously (EFSA, 2011a) and considered that the outcome of the exposure estimates for these three minor constituents of caramel colours did not give rise to public health concern and that maximum levels have been established for THI, 4-MEI and sulphur dioxide in the specifications of the relevant caramel colours (Commission Regulation (EU) N° 231/2012[9]) the present statement does not present any new exposure estimates for these constituents.

2. Uses and use levels of caramel colours

The main use of the caramel colours is to impart a brown colour and associated characteristic caramel flavour to the foods to which they are added. They are used in a wide range of foodstuffs including

[9] Commission Regulation (EU) N° 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p. 1–295

non-alcoholic flavoured drinks (especially cola-type), alcoholic drinks such as beer and cider, spirits (e.g. whiskey), cereals and bakery wares, soups, sauces and gravies, decorations and coatings, confectionary, meat and fish analogues.

In addition, caramel colours are used in cosmetics and pharmaceutical products as well as in feed.

2.1. Maximum Permitted Levels of use

Maximum Permitted Levels (MPLs) of use for the caramel colours have been defined in the Commission Regulation (EU) N° 1129/2011[10] on food additives for use in foodstuffs.

Caramel colours are authorised as food colours at quantum satis[11] (QS) level in the EU. In addition, caramel colours are included in the Group II of food additives authorised for use at QS, as defined in the Commission Regulation (EU) N° 1129/2011 and may therefore also be used in the food categories in which Group II food additives are allowed.

Table 2 summarises the food categories that are permitted to contain caramel colours in accordance to Commission Regulation (EU) N° 1129/2011.

Table 2: Food categories in which caramel colours (E 150a, E 150b, E 150c, E 150d) are authorised to be used as food additives at QS level according to the Commission Regulation (EU) N° 1129/2011

Category No	Food categories	E Number/ Group	Name/ Group name	Restrictions/exception
1.4	**Flavoured fermented milk products including heat treated products**	Group II	Colours	
1.5	**Dehydrated milk as defined by Directive 2001/114/EC**	Group II	Colours	except unflavoured products
1.6.3	**Other creams**	Group II	Colours	only flavoured creams
1.7.1	**Unripened cheese excluding products falling in category 16**	Group II	Colours	only flavoured unripened cheese
1.7.3	**Edible cheese rind**	Group II	Colours	
1.7.4	**Whey cheese**	Group II	Colours	
1.7.5	**Processed cheese**	Group II	Colours	only flavoured processed cheese
1.7.6	**Cheese products (excluding products falling in category 16)**	Group II	Colours	only flavoured unripened products
1.8	**Dairy analogues, including beverage whiteners**	Group II	Colours	
3.	**Edible ices**	Group II	Colours	
4.2.1	**Dried fruit and vegetables**	E 150a/b/c/d	Caramels	only preserves of red fruit
4.2.2	**Fruit and vegetables in vinegar, oil, or brine**	E 150a/b/c/d	Caramels	only preserves of red fruit
4.2.2	**Fruit and vegetables in vinegar, oil, or brine**	E 150a/b/c/d	Caramels	only vegetables (excluding olives)
4.2.3	**Canned or bottled fruit and vegetables**	E 150a/b/c/d	Caramels	only preserves of red fruit
4.2.4.1	**Fruit and vegetable preparations excluding compote**	Group II	Colours	only mostarda di frutta

[10] Commission Regulation (EU) N° 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) N°1333/2008 of the European Parliament and of the Council establishing a Union list of food additives. . OJ L 295, 12.11.2011, p. 1–177. The Panel noted that the Commission Regulation (EC) N° 1129/2011 of 11 November 2011 will enter into force on June, 1st 2013 but confirms the approved uses of caramels as food additives as described in Council Directive N° 94/36/EC of 30 June 1994 on colours for use in foodstuffs.

[11] According to the Regulation (EC) N°1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16–33), 'quantum satis' shall mean that no maximum numerical level is specified and substances shall be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided the consumer is not misled.

Category No	Food categories	E Number/ Group	Name/ Group name	Restrictions/exception
4.2.4.1	**Fruit and vegetable preparations excluding compote**	E 150 a/b/c/d	Caramels	only preserves of red fruit
4.2.5.2	**Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EEC**	E 150a/b/c/d	Caramels	except chestnut puree
4.2.5.3	**Other similar fruit or vegetable spreads**	Group II	Colours	except *crème de pruneaux*
5.2	**Other confectionery including breath freshening microsweets**	Group II	Colours	
5.3	**Chewing gum**	Group II	Colours	
5.4	**Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4**	Group II	Colours	
6.3	**Breakfast cereals**	Group II	Colours	only breakfast cereals other than extruded, puffed and/or fruit flavoured breakfast cereals
6.3	**Breakfast cereals**	E 150c	Ammonia caramel	only extruded puffed and or fruit flavoured breakfast cereals
6.5	**Noodles**	Group II	Colours	
6.6	**Batters**	Group II	Colours	
6.7	**Pre-cooked or processed cereals**	Group II	Colours	
7.1.	**Bread and rolls**	E 150a/b/c/d	Caramels	only Malt bread
7.2	**Fine bakery wares**	Group II	Colours	
8.1.2	**Meat preparations as defined by Regulation (EC) No 853/2004**	E 150a/b/c/d	Caramels	only *breakfast sausages* with a minimum cereal content of 6 % and *burger meat* with a minimum vegetable and/or cereal content of 4 % mixed within the meat; In these products, the meat is minced in such a way so that the muscle and fat tissue are completely dispersed, so that fibre makes an emulsion with the fat, giving those products their typical appearance
8.2.1	**Non heat treated processed meat**	E 150a/b/c/d	Caramels	only sausages
8.2.2	**Heat treated processed meat**	E 150a/b/c/d	Caramels	only sausages, patés and terrines
8.2.3	**Casings and coatings and decorations for meat**	Group II	Colours	except edible external coating of pasturmas
9.2.	**Processed fish and fishery products including molluscs and crustaceans**	Group II	Colours	only surimi and similar products and salmon substitutes.
9.2.	**Processed fish and fishery products including molluscs and crustaceans**	E 150a/b/c/d	Caramels	only fish paste and crustacean paste
9.2.	**Processed fish and fishery products including molluscs and crustaceans**	E 150a/b/c/d	Caramels	only precooked crustacean
9.3	**Fish roe**	Group II	Colours	except Sturgeons' eggs (Caviar)
12.2.2	**Seasonings and condiments**	Group II	Colours	only seasonings, for example curry powder, tandoori
12.3	**Vinegars**	E 150a/b/c/d	Caramels	
12.4	**Mustard**	Group II	Colours	
12.5	**Soups and broths**	Group II	Colours	
12.6	**Sauces**	Group II	Colours	excluding tomato-based sauces
12.7	**Salads and savoury based sandwich spreads**	Group II	Colours	
12.9	**Protein products, excluding products covered in category 1.8**	Group II	Colours	

Category No	Food categories	E Number/ Group	Name/ Group name	Restrictions/exception
13.2	**Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)**	Group II	Colours	products in this category can also use additives that are allowed in the corresponding food counterparts categories
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 II	Colours	
13.4	**Foods suitable for people intolerant to gluten as defined by Regulation (EC) 41/2009**	Group II	Colours	products in this category can also use additives that are allowed in the corresponding food counterparts categories. In addition, all additives in the gluten containing counterparts are authorised.
14.1.4	**Flavoured drinks**	Group II	Colours	excluding chocolate milk; malt products
14.2.1	**Beer and malt beverages**	E 150a/b/c/d	Caramels	only beer
14.2.3	**Cider and perry**	Group II	Colours	excluding *cidre bouché*
14.2.3	**Cider and perry**	E 150a/b/c/d	Caramels	only *cidre bouché*
14.2.4	**Fruit wine and made wine**	Group II	Colours	
14.2.5	**Mead**	Group II	Colours	
14.2.6	**Spirit drinks as defined in Regulation (EC) No 110/2008**	Group II	Colours	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.
14.2.6	**Spirit drinks as defined in Regulation (EC) No 110/2008**	E 150a/b/c/d	Caramels	except: fruit spirits, spirits (preceded by the name of the fruit) obtained by maceration and distillation, London Gin, Sambuca, Maraschino, Marrasquino or Maraskino and Mistrà. Whisky, whiskey can only contain E 150a.
14.2.7.1	**Aromatised wines**	Group II	Colours	except *americano, bitter vino*
14.2.7.1	**Aromatised wines**	E 150a/b/c/d	Caramels	
14.2.7.1	**Aromatised wines**	E 150a/b/c/d	Caramels	only *americano, bitter vino*
14.2.7.2	**Aromatised wine-based drinks**	Group II	Colours	except *bitter soda, sangria, claria, zurra*
14.2.7.2	**Aromatised wine-based drinks**	E 150a/b/c/d	Caramels	only *bitter soda*
14.2.7.3	**Aromatised wine-product cocktails**	Group II	Colours	
14.2.8	**Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% of alcohol**	Group II	Colours	
15.1	**Potato-, cereal-, flour- or starch-based snacks**	Group II	Colours	
15.2	**Processed nuts**	Group II	Colours	
16	**Desserts excluding products covered in category 1, 3 and 4**	Group II	Colours	
17.1	**Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms**	Group II	Colours	

Category No	Food categories	E Number/ Group	Name/ Group name	Restrictions/exception
17.2	**Food supplements supplied in a liquid form**	Group II	Colours	
17.3	**Food supplements supplied in a syrup-type or chewable form**	Group II	Colours	

2.2. Reported use levels of caramel colours

In the EU most food additives are authorised at a specific MPL. However, a food additive may be used at a lower level than the MPL. For those additives where no MPL is set and which are authorised at QS, information on actual use levels is required. When no use levels are made available, the ANS Panel defined some rules to deal with QS (Appendix A, Figure 2). As a first step, it implies using the levels proposed by the Codex Alimentarius in its General Standard for Food Additives database (GSFA database). This database provides MPLs for caramel colours E 150c and E 150d; no maximum levels are set forth for caramel colour E 150a. It has to be mentioned that in the previous ANS Panel opinion (EFSA, 2011a), MPLs from the GSFA database were not considered. However, to re-evaluate food additives authorised at QS, it appeared that other data from regulatory sources should be used. Therefore, the levels of caramel colours used for the current exposure estimates could be higher than the ones used in the previous ANS Panel opinion (EFSA, 2011a) because coming from Codex's MPLs: e.g. for aromatised wines, food supplements, mustard. The second step is to use available values for the same food categories among other colours which are authorised in Commission Regulation (EU) N° 1129/2011.

Updated information on the actual use levels of the caramel colours in foods was made available to EFSA for several food categories of finished products by FoodDrinkEurope and the European Technical Caramel Association (EUTECA) (Appendix B). No analytical data from other sources (Member States, scientific literature) were collected. Appendix B also shows the levels used for the refined exposure assessment identified by EFSA using rules defined by the ANS Panel, based either on the data provided by industry or from the rules set to deal with QS authorisation, as indicated in Appendix A (Figures 1 and 2).

Summarised data on reported use levels of caramel colours in foods from industries

The data provided cover the main food categories in which caramel colours are authorised to be added: both non-alcoholic (e.g. flavoured drinks) and alcoholic beverages (e.g. beer), sauces and seasonings, confectionary, bakery wares and breakfast cereals, dairy products, snacks and desserts. Some clarifications with the data provider took place in September and October 2012 in order to ensure that the data were correctly used within the food additive nomenclature.

Unlike the previous data used in the 2011 ANS Panel opinion, information provided by industry is presented as "gathered from industries operating at the end of the supply chain". Therefore the levels should reflect the actual levels of use in food products as consumed. For most of the food categories, two use levels were provided: a typical or usual use level and an extreme use level. The present exposure assessment follows a conservative approach, using the extreme reported use levels for the calculations. Some information could also be gained from the data provided relating to how representative some use levels were for the European market or with regards to the specific foods in which these use levels actually apply. Thus, extreme use levels reported for niche products (e.g. very specific products eaten in one country) were not taken into account in the exposure estimates.

For some food categories, no use levels were provided by industry i.e. for the three caramel colours E 150a, E 150c and E 150d for several fruit and vegetables categories (dried, in oil or brine, canned or bottled, preparations excluding compote), chewing gum, batters, processed cereals, fruit wine and made wine, mead, aromatised wines and aromatised wine-based drinks, aromatised wine-product cocktails and other alcoholic drinks incl. mixtures of alcoholic drinks with non-alcoholic drinks and

spirits, food supplements. Furthermore, no data were provided for caramel colour E 150a for processed meat, processed fish, vinegars, cider and perry, for caramel colour E 150c for processed cheese, mustard, salads and savoury spreads, protein products, dietary foods for weight control, for caramel colour E 150d for processed cheeses, noodles, vinegars, mustard, soups and broths, protein products, dietary foods for weight control, other alcoholic drinks and desserts.

For some of the products above mentioned, the MPLs from the Codex Alimentarius were considered too high due to technological issues which according to the industry, may include stability challenges (due to the interaction of caramel colours with milk proteins, or to their interaction with the salt in the food matrix, or for caramel colour E 150c to interaction in alcoholic drinks with the product due to its colloidal charge under acidic conditions) or because a high level of caramel colours in the food product would render its colour not acceptable (e.g. black/opaque). Therefore, EFSA used the levels provided for other caramel colours for the same food category as a conservative approach. This applies to the following food groups: whey and processed cheese, noodles, soups and broths, salads and savoury based sandwich spreads, other alcoholic drinks and desserts.

Use levels for the remaining food categories (i.e. aromatised wines, some fruit and vegetable products, meat and fish preparations, food supplements, mustard and vinegars) followed the rules defined by the ANS Panel as described above.

For some food categories, the use levels currently provided are far lower than the ones used in the previous exposure estimate (EFSA, 2011a). One of the major changes in the use levels is for seasonings and condiments, soups, sauces and vinegars, where the use levels provided in 2012 are lower by a factor of 5 to 200 according to the caramel colour and the food group. For the flavoured fermented milk products for the three caramel colours: the actual use levels are lower by a factor of 20 to 35. Lower use levels were also provided for bakery wares and breakfast cereals (by a factor of 2 to 10). Use levels of caramel colours E 150 a and E 150c provided for flavoured drinks were also lower by a factor of 2 to 7, and different use levels were provided for the caramel colours E 150d according to the kind of soft drinks (cola-type or not). Caramel colour E 150a use levels were lower than in the previous ANS Panel opinion for aromatised alcoholic drinks.

The use levels used in the previous ANS Panel opinion and in the present exposure estimate are presented in the Appendix B.

3. Food consumption

3.1. EFSA's Comprehensive European Food Consumption Database

In 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been built from existing national information on food consumption at a detailed level. Competent authorities in each European country provided 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, 2011b).

Overall, the food consumption data gathered at EFSA were collected by different methodologies and thus direct country-to-country comparison should be made with caution.

Consumption records were codified according to the FoodEx classification system (EFSA, 2011c). Nomenclature from FoodEx classification system has been linked to the Food Classification System (FCS), as presented in the Commission Regulation (EU) N° 1129/2011, part D, to perform exposure estimates.

3.2. Food items selected for the refined exposure assessment of caramel colours

The food categories in which the use of caramel colours (E 150a, E 150c, E 150d) is authorised were selected from the nomenclature of the Comprehensive Database (FoodEx classification system codes), at a detailed level (up to FoodEx level 4) (EFSA, 2011b).

Some of the food categories in which the use of food colours is permitted at QS (Group II food additives) are very unlikely to contain caramel colours and therefore it was decided not to take them into account. Other food items were 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 estimates.

The food categories which were not taken into account in the present exposure assessment are described below (in ascending order of the Food Classification System codes):

- **1.5. Dehydrated milk as defined by Directive 2001/114/EC, except unflavoured products**: this food category corresponds to dried or condensed milk, products which are unlikely to contain colours such as caramel colours. Only unflavoured dehydrated milks are included in the corresponding category in FoodEx.

- **1.7.4. Whey cheese:** this food category corresponds to cheeses such as ricotta and mizithra which are unlikely to contain caramel colours.

- **1.7.6. Cheese products (excluding products falling in category 16), only flavoured unripened products:** all flavoured cheeses or analogues are gathered under "processed cheese" (category number 1.7.5), no food items correspond to this category in the FoodEx category.

- **4.2.4.1. Fruit and vegetable preparations excluding compote, only *mostarda di frutta*:** this item is not referenced in the FoodEx nomenclature, even at the original food name level. Therefore, it was not taken into account. Considering that this is a niche product, this leads to a minor underestimation of the total exposure.

- **5.4. Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4:** This category covers any confectionery product generally used for decorating and filling any foodstuff 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 filled or decorated (e.g. bakery wares) are included in the assessment.

- **6.6. Batters:** as for decorations and coatings, batters represent a part of a composite food and are not referenced in the FoodEx nomenclature. This category was not taken into account in the present estimates.

- **6.7. Pre-cooked or processed cereals:** this category covers pre-cooked and processed rice products, including rice cakes (Oriental type only) and other pre-cooked cereals such as quick-cook rice, *polenta* and *Semmelknödelteig.* No information on the processed status (cooked, treated) of cereals is available in the FoodEx nomenclature. Therefore, this food category was not taken into account in the present assessment.

- **7.1. Bread and rolls, only malt bread:** Malt bread is a niche product almost only consumed in UK. This food item is not referenced in the FoodEx nomenclature and is not taken into account in the present evaluation.

- **8.2.3. Casings and coatings and decorations for meat, except edible external coating of pasturmas:** as for decorations and coatings, these represent a part of composite foods (such as sausages, category number 8.2.1). Moreover, casings and coatings for meat are not referenced

in the FoodEx nomenclature. This category was not taken into account in the present estimates.

- **13.4. Foods suitable for people intolerant to gluten:** this category was not taken into account in this estimate. Since people who require such foods do not follow the same diet as the general population, exposure estimates specifically for people intolerant to gluten are not in the scope of the present statement.

- **14.2.4. Fruit wine and made wine:** this category includes wine made from fruits other than grapes and apples and from other agricultural products, including grains; it may be still or sparkling (e.g. rice wine, sake). No such category of wines is present in the FoodEx nomenclature.

Other limitations of the current exposure estimates, which are due to the linkage between the FoodEx classification system and the Food Classification System (Commission Regulation (EU) N° 1129/2011), are listed below (in ascending order of FCS codes). It results in overestimations, most often minor, of the exposure estimate:

- **1.7.3. Edible cheese rind:** no consumption data for cheese rind were available in the Comprehensive Database. However, in order to take this category into account, it was assumed that cheese rind corresponds to 10% of ripened cheese, and that consumers always eat the rind, assumptions which are conservative.

- **4.2.5.2. Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EEC, *except chestnut purée,*** as well as **4.2.5.3. Other similar fruit or vegetable spreads, *except crème de pruneaux*:** the exception of the specific products chestnut purée or crème de pruneaux could not be taken into account, therefore all jam, jellies and marmalades or purée and other spreads made from fruits and vegetables were included in the present estimate.

- **8.1.2. Meat preparations, *only breakfast sausages*:** all sausages were included in the estimation taking as a reference the use level of non-heated treated processed meat (category number 8.2.1).

- **9.2. Processed fish and fishery products including molluscs and crustaceans, *only surimi and similar products and salmon substitutes, only fish paste and crustacean paste*:** all processed fish products (such as fish paste, fish fingers) were included in the present estimate.

- **9.2. Processed fish and fishery products including molluscs and crustaceans, *only pre-cooked crustaceans*:** since no information on the processing of food items is available within the Comprehensive Database, all crustaceans were included in the present estimate.

- **14.1.3. Cider and perry:** no distinction was possible between cider and *cidre bouché*, therefore, the category was accounted for as a whole.

- **14.1.4. Flavoured drinks, *excluding chocolate milk, malt products*:** One of the main uses of caramel colours is in non-alcoholic beverages (soft drinks). Within this food category, caramel colours are mostly used in cola-flavoured carbonated drinks. Caramel colours are also used at lower levels in some other soft drinks. With the help of ingredients databases (Irish[12] and German[13] databases), a list of non cola-type soft drinks that may contain caramel colours (ginger-ale, ice-tea, energy-drinks, blackcurrant soft drinks) was made. The correspondent food items in the FoodEx nomenclature were selected. No blackcurrant flavour soft drink item

[12] Irish Universities Alliance (2008-2010) Irish National Food Ingredients Database Version 3 (NANS).
[13] BfR. Database on food additives as labelled on foods reported in German consumption surveys for children. Database was developed by BfR subcontracting University of Paderborn. Publication is foreseen for 2013.

exists as such in the FoodEx nomenclature, but some could be classified under the parental food category as unclassified soft drinks, therefore all non-classified soft drinks were taken into account. Then, the use level specifically reported for cola-type drinks was applied to beverages classified as cola-type in the FoodEx nomenclature, whereas another use level reported for other type of soft drinks (lower than for cola-type drinks) was applied to the other selected drinks within the non-alcoholic beverages category. Chocolate milk, malt products were not taken into account.

- **14.2.5. Mead:** it is not referenced as such in the FoodEx nomenclature. Mead is included in the cider food item and was taken into account within this food item.

- **17.1/17.2/17.3. Food supplements:** no distinction between the forms of the food supplements is possible within the FoodEx nomenclature, therefore these three food categories were considered as a whole and the highest reported use levels were taken into account.

For food categories not mentioned above, foods from the Comprehensive Database were chosen in accordance with the legislation (Table 2).

4. Dietary exposure assessment

Dietary exposure to caramel colours from their use as food colours was estimated based on the consumption data available within the Comprehensive Database as presented in Section 3.2., and with the limitations described below.

For calculation of chronic exposure, intake statistics have been calculated based on individual consumption over the total survey period, excluding surveys with only one day per subject, considered as not adequate to assess repeated dietary exposure, as suggested by the EFSA Working group on Food Consumption and Exposure (EFSA, 2011b).

Chronic exposure to caramel colours (E 150a, E 150c and E 150d) 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 mentioned in Table 3.

Table 3: Population groups considered for the exposure estimates of caramel colours

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[14]	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[14]	Older than 65 years	Belgium, Denmark, Finland, France, Germany, Hungary, Italy

[14] 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, 2011b).

High level consumption was only calculated for those foods and population groups were the sample size was sufficiently large to allow calculation of the 95th percentile (EFSA, 2011b). Therefore, in the present estimate, high levels for toddlers from Belgium, Italy and Spain were not included.

In summary, FoodEx food codes were matched to the food categories reported in Table 2 and subsequently each individual exposure was calculated by using the corresponding individual body weight and based on the assumption that caramel colours are present in the food at the levels shown in Appendix B. The average and high percentile exposures were calculated for the total population, for the five population groups described in Table 3.

4.1. Exposure to caramel colours from their use as food additives

Table 4 summarises the anticipated refined estimated exposure to caramel colours from their use as food additives for all five population groups.

Table 4: Summary of refined exposure to caramel colours (E 150a, E 150c, E 150d) in five population groups (mg/kg bw/day)

	Toddlers (12-35 months)	Children (3-9 years)	Adolescents (10-17 years)	Adults (18-64 years)	The elderly (> 65 years)
Caramel colour E 150a					
• Mean	11-45	15-39	6-24	6-18	4-12
• High level (95th percentile)	32-79	36-81	16-56	16-42	13-32
Caramel colour E 150c					
• Mean	10-60	20-56	9-33	10-43	6-30
• High level (95th percentile)	36-106	43-97	20-86	27-151	14-82
Caramel colour E 150d					
• Mean	11-86	19-62	8-44	9-36	6-22
• High level (95th percentile)	38-127	49-136	21-122	26-101	19-60

As a reminder, Table 5 presents the dietary exposures to caramel colours E 150a, E 150c and E 150d as estimated in ANS Panel opinion in 2011 for the two population groups: children and adults.

Table 5: Summary of anticipated exposure to caramel colours E 150a, E 150c and E 150d in children and adult populations as calculated in the previous ANS Panel opinion (EFSA, 2011a) (mg/kg bw/day)

	Children (1-14 years)	UK Adults (> 18 years)
Caramel colour E 150a		
• Mean	77-427	137
• High level (97.5th percentile)	180-882	429
Caramel colour E 150c		
• Mean	22-302	61
• High level (97.5th percentile)	108-757	295
Caramel colour E 150d		
• Mean	23-506	89
• High level (97.5th percentile)	130-1480	369

4.2. Main food categories contributing to exposure of caramel colours

Table 6: Main food categories contributing to mean exposure to caramel colour E 150a (> 5% of total exposure) using reported use levels and number of surveys in which each food category is a main contributor.

Cat N°	Foods*	% contribution to total exposure (Number of Surveys)**				
		Toddlers	**Children**	**Adolescents**	**Adults**	**The elderly**
7	**Bakery wares**	**5.4-67.3 (7)**	**5.7-63.9 (15)**	**4.8-52.6 (12)**	11.0-42.4 (13)	5.6-41.8 (6)
12	**Salts, spices, soups, sauces, salads and protein products**	5.6-41.7 (6)	6.3-33.1 (14)	6.4-24.2 (10)	6.9-53.5 (14)	**7.3-57.9 (7)**
1	Dairy products and analogues	10.9-31.4 (6)	5.4-14.1 (8)	5.5-6.0 (2)	7.7 (1)	5.1 (1)
14.1	**Non-alcoholic beverages**	7.8-28.5 (3)	**5.4-43.3 (15)**	**13.3-51.1 (12)**	**6.7-46.3 (15)**	8.0 -39.2 (2)
6	Cereals and cereal products	5.8-8.6 (3)	5.3-12.3 (6)	11.1 (1)	7.8-9.4 (2)	10.5 (1)
16	Desserts excluding products covered in category 1, 3 and 4	6.5-23.2 (3)	6.9-14.5 (5)	5.1-7.9 (2)	5.8-5.9 (2)	7.2 (1)
15	Ready-to-eat savouries and snacks	6.1-8.4 (2)	5.0-6.3 (3)	5.2-9 (5)		
5.2	Other confectionery including breath refreshening microsweets	7.7 (1)	5.2-16 (8)	5.0-14.1 (5)	7.4-9.4 (2)	
3	Edible ices	5.9-18.2 (2)	5.0-15.4 (9)	6.4-7.3 (2)	5.2 (1)	
4	Fruit and vegetables	5.1 (1)			5.0 (1)	5.2-10.1 (6)
14.2	**Alcoholic beverages, including alcohol-free and low-alcohol counterparts**			5.6-6.4 (3)	**9.3-44.6 (15)**	**6.1-34.4 (7)**

* Food groups in bold exceed 5% contribution to total exposure in population groups.

** Total number of surveys may be greater than 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 mean exposure to caramel colour E 150c (> 5% of total exposure) using reported use levels and number of surveys in which each food category is a main contributor.

Cat N°	Foods*	% contribution to total exposure (Number of Surveys)**				
		Toddlers	**Children**	**Adolescents**	**Adults**	**The elderly**
7	**Bakery wares**	**6.5-55.7 (7)**	**5.6-60.6 (15)**	15.7-47.6 (11)	6.8-28.5 (13)	11.6-34.2 (2)
1	**Dairy products and analogues**	**6.4-25.8 (7)**	5.3-14 (11)	5.1-30.4 (10)	5.1-13.5 (10)	**5.1-24.8 (7)**
8	Meat	5.2-26.2 (6)	5.6-29.3 (14)	7.7-17.2 (10)	5.4-28.9 (11)	5.2-28.8 (6)
12	Salts, spices, soups, sauces, salads and protein products	7.3-40.4 (6)	8.8-40.4 (13)	6.4-41.4 (11)	5.2-37.3 (14)	11.1-30.1 (6)
5.2	Other confectionery including breath refreshening microsweets	6.3-8.3 (2)	6.3-19.8 (2)	5.4-17.9 (8)	5.8-6.2 (2)	
15	Ready-to-eat savouries and snacks	5.2 (1)		6.2 (1)		
6	Cereals and cereal products	12.6 (1)	5.1-11.2 (5)	10.4 (1)	6.2 (1)	8.6 (1)
14.1	Non-alcoholic beverages	7.1 (1)	5.1-12.6 (4)	5.1-15.1 (7)	8.4 (1)	6.3 (1)
14.2	**Alcoholic beverages, including alcohol-free and low-alcohol counterparts**			6.5-24.3 (6)	**23-73.2 (15)**	**11.8-71.9 (7)**
16	Desserts excluding products covered in category 1, 3 and 4	9.0-26.7 (3)	7.0-21 (5)	5.1-10.1 (3)		5.4 (1)
3	Edible ices	5.0 (1)				
4	Fruit and vegetables	9.6-18.9 (2)	6.2 (1)			
7	Fish and fisheries products	5.0 (1)	10.3 (1)	7.2 (1)		

* Food groups in bold exceed 5% contribution to total exposure in population groups.

** Total number of surveys may be greater than total number of countries as listed in Table 3, as some countries submitted more than one survey for a specific age range.

High level exposures for toddlers may slightly exceed the ADI of 100 mg/kg bw/day for caramel colour E 150c. The food categories contributing to this exceedance are desserts and bakery wares, i.e. the fine bakery wares (pastries and cakes, biscuits and cereal bars) within the later food category.

For adults, the ADI is exceeded in 5 countries out of 15: from 105% to 151% (Appendix C). The food category which contributes the most leading to an exceedance of the ADI is alcoholic beverages with a contribution from 23 to 73% in all countries. In the 5 countries exceeding the ADI, fine bakery wares also contribute to more than 5% (up to 11%) of the total mean exposure to caramel colour E 150c; salts, spices, soups, sauces, salads and protein products food category, and within this food category especially sauces, and soups and broth, were also contributing to more than 5% in 4 countries (up to 12%).

Table 8: Main food categories contributing to mean exposure to caramel colour E 150d (>5% of total exposure) using reported use levels and number of surveys in which each food category is a main contributor

Cat N°	Foods*	% contribution to total exposure (Number of Surveys)**				
		Toddlers	Children	Adolescents	Adults	The elderly
12	**Salts, spices, soups, sauces, salads and protein products**	**10.5-31.8 (7)**	**10.8-45.7 (15)**	10.5-47.1 (11)	**10.4-55.7 (15)**	**9.7-44.7 (7)**
1	**Dairy products and analogues**	**5.8-26.2 (7)**	5.1-13.8 (11)	5.3-34.8 (8)	5.3-15.2 (13)	**5.7-22.0 (7)**
7	Bakery wares	6.4-27.7 (6)	7.8-32.8 (13)	6.3-19.1 (11)	5.1-14.8 (11)	6.3-16.4 (5)
5.2	Other confectionery including breath refreshening microsweets	6.5-19.0 (5)	5.1-31.2 (12)	8.4-29.8 (7)	5.7-20.2 (5)	8.6-8.7 (2)
14.1	**Non-alcoholic beverages**	5.5-39.3 (4)	**8.5-36.2 (15)**	**14.0-51.8 (12)**	**7.9-44.7 (15)**	5.7-44.0 (4)
3	Edible ices	8.0-27.5 (4)	5.4-22.0 (14)	5.4-12.5 (8)	6.0-8.6 (3)	7.2 (1)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts			5.9-8.7 (2)	6.0-37.3 (10)	11.6-30.1 (4)
16	Desserts excluding products covered in category 1, 3 and 4	6.3-37.9 (3)	5.3-17.6 (6)	5.7-9.7 (3)	5.4 (1)	6.4 (1)
4	Fruit and vegetables	10.7-18.2 (2)	6.5 (1)	5.0 (1)	5.4-21.0 (3)	12.8-26.7 (2)
8	Meat	5.8-11.1 (3)	5.5-7.7 (6)	5.7-7.3 (5)	5.7-10.9 (4)	6.1-11.7 (3)
17	Food supplements as defined in Directive 2002/46/EC[15] excluding food supplements for infants and young children					6.3 (1)

* Food groups in bold exceed 5% contribution to total exposure in population groups.

** Total number of surveys may be greater than total number of countries as listed in Table 3, as some countries submitted more than one survey for a specific age range.

4.3. Combined refined exposure to caramel colours

A refined combined dietary exposure estimate was also calculated for the four caramel colours (E 150a, E 150b, E 150c, E 150d), by selecting within each food category, the highest use level among the use levels reported for the four caramel colours. Caramel colour E 150b use levels used in the combined refined exposure are the ones used in the previous ANS Panel opinion (EFSA, 2011a)

This scenario represents an additional uncertainty in the combined exposure estimates, by assuming, on one hand, that caramel colours are present in each food category at the highest use level reported and on the other hand by not taking into account that more than one caramel colours may be added in the same food product.

[15] Directive 2002/46/EC of the European Parliament and Council of 10 June 2002 on the approximation of the laws of Member States relating to food supplements. OJ L OJ L 183, 12.7.2002, p. 51-57.

Table 9: Summary of anticipated refined combined exposure to all four caramel colours in the five population groups (mg/kg bw/day).

Combined exposure to caramel colours E 150a, E 150b, E 150c, E 150d	Toddlers (12-35 months)	Children (3-9 years)	Adolescents (10-17 years)	Adults (18-64 years)	The elderly (> 65 years)
• Mean	19-105	31-83	12-56	15-57	9-35
• High level (95th percentile)	73-158	68-160	28-144	41-165	24-87

As a reminder, Table 9 presents the combined dietary exposures to caramel colours as estimated in ANS Panel opinion in 2011 for the two population groups: children and adults.

Table 10: Summary of anticipated combined exposure to all four caramel colours in children and adult populations as calculated in the previous ANS Panel opinion (EFSA, 2011a) (mg/kg bw/day)

Combined exposure to caramel colours E 150a, E 150b, E 150c, E 150d	Children (3-9 years)	Adults (18-64 years)
• Mean	83-698	195
• High level (95th percentile)	225-1672	474

Table 11: Main food categories contributing to the mean combined exposure to caramel colour E 150a, E 150b, E 150c and E 150d using reported use levels and number of surveys in which each food category is a main contributor.

Cat Nº	Foods*	% contribution to total exposure (Number of Surveys)**				
		Toddlers	Children	Adolescents	Adults	The elderly
1	**Dairy products and analogues**	**10.1-25.1 (7)**	5.2-11.1 (13)	5.0-23.8 (7)	5.1-10.3 (6)	5.4-16.5 (4)
12	**Salts, spices, soups, sauces, salads and protein products**	**6.4-24.4 (7)**	**7.1-34.1 (15)**	8.5-34.7 (11)	**5.6-34.5 (15)**	18.7-31.5 (6)
7	Bakery wares	11.4-41.3 (6)	11.7-44.6 (13)	10.6-28.5 (11)	6.3-17.7 (12)	9.0-21.3 (5)
8	Meat	7.0-17.2 (5)	5.6-13.5 (13)	5.3-12.6 (9)	5.3-17.8 (8)	6.8-18.9 (3)
5.2	Other confectionery including breath refreshening microsweets	6.1-14.2 (4)	5.7-25.4 (10)	6.4-23.5 (7)	5.1-10.8 (3)	5.4 (1)
14.1	**Non-alcoholic beverages**	5.8-31.9 (3)	**5.5-27.8 (15)**	**9.7-40.3 (12)**	6.0-27.5 (14)	5.9-19.1 (2)
3	**Edible ices**	8.4-26.3 (4)	**5.3-23.2 (15)**	5.0-14.2 (10)	5.8-7.9 (3)	7.8 (1)
14.2	**Alcoholic beverages, including alcohol-free and low-alcohol counterparts**			8.3-15.8 (4)	**17.9-63.9 (15)**	**8-56.1 (7)**
16	Desserts excluding products covered in category 1, 3 and 4	5.1-23.1 (3)	5.9-13.5 (5)	7.0 (1)		
4	Fruit and vegetables	8.1-11.5 (2)	5.6 (1)		14.9 (1)	10.3-19.3 (2)
6	Cereals and cereal products	6.6 (1)	7.6 (1)	8.1 (1)		5.6 (1)
9	Fish and fisheries products		6.5 (1)			

* Food groups in bold exceed 5% contribution to total exposure in population groups.

** Total number of surveys may be greater than total number of countries as listed in Table 3, as some countries submitted more than one survey for a specific age range.

5. Results and discussion

EFSA has performed a refined exposure assessment for caramel colours (E 150a, E 150c, E 150d) taking into consideration newly submitted reported use levels provided by industry (FoodDrinkEurope, 2012; FoodDrinkEurope-EUTECA, 2012).

The present refined exposure estimates have been performed using the maximum reported use levels, or, where these were not reported, the MPLs from the Codex Alimentarius. When Codex Alimentarius MPLs were not available, values defined by decision rules for QS usages (Appendix A, figure 2) were used (Appendix B).

The results of the present exposure assessment to caramel colours E 150a, E 150b and E 150d are considerably lower than those from the previous exposure assessment performed by the ANS Panel in 2011 (EFSA, 2011a).

For caramel colour E 150a, toddlers and children have higher dietary exposures than adolescents, adults and the elderly. The mean dietary exposures for toddlers and children range respectively from 11 to 45 mg/kg bw/day and from 15 to 39 mg/kg bw/day; the 95th percentile anticipated exposures range respectively from 32 to 79 mg/kg bw/day and from 36 to 81 mg/kg bw/day. For adolescents, adults and the elderly, the anticipated dietary exposure to caramel colour E 150a gives a range through all European countries of 4 to 24 mg/kg bw/day at the mean and of 13 to 56 mg/kg bw/day at the 95th percentile. Compared to the previous ANS Panel opinion (EFSA, 2011a), exposures of children are 5 to 11 times lower both at the mean and at the high level. Current exposures for adults are around 10 to 20 times lower than the estimated exposures from previous ANS Panel opinion.

The main contributors (contributing > 5% of the total exposure in all or several countries) to the total mean exposure to caramel colour E 150a for toddlers are bakery wares (> 5 % in all surveys: from 5 to 67%); for children and adolescents, bakery wares are also a main contributor together with non-alcoholic beverages (> 5 % in all surveys). For adults, beverages (alcoholic and non-alcoholic) are the main contributing food categories (> 5 % in all surveys). For the elderly, salt, spices, soups and sauces and alcoholic beverages are the main contributing food categories. The same foods groups contributed the most in the previous exposure estimates (EFSA, 2011a) both for children and adults.

For caramel colour E 150c, anticipated exposures of toddlers and children are quite similar: estimates range from 10 to 60 mg/kg bw/day and from 36 to 106 mg/kg bw/day for toddlers, and for children from 20 to 56 mg/kg bw/day and from 43 to 97 mg/kg bw/day, for mean and high levels respectively. The anticipated exposures to E 150c for adolescents and the elderly are also similar: from 6 to 33 mg/kg bw/day at the mean and from 14 to 86 mg/kg bw/day at the 95th percentile. The anticipated exposures for adults range from 10 to 43 mg/kg bw/day at the mean and from 27 to 151 mg/kg bw/day at the 95th percentile. Compared to the previous ANS Panel opinion, the results of the current exposures are 5 times lower at the mean and from 2 to 10 times lower for the high level exposure estimates for both children and adults.

For caramel colour E 150c, the main contributors to the total mean exposure for toddlers are bakery wares and dairy products (> 5 % in all surveys). For children, bakery wares are also the food category contributing the most (> 5 % in all surveys). In the previous ANS Panel opinion, fine bakery wares were also the main contributing food category, together with desserts, and sauces and seasonings. Alcoholic beverages are a major contributing food category for adults and the elderly (> 5 % in all surveys). Dairy products are the second food category contributing most for the elderly. Beer and cider were the food category contributing most in the previous exposure estimates for adults, sauces with seasoning being the second one.

Mean anticipated exposures of toddlers, children and adolescents to caramel colour E 150d range respectively from 11 to 86 mg/kg bw/day, from 19 to 62 mg/kg bw/day and from 8 to

44 mg/kg bw/day at the mean. At the 95th percentile, exposures range from 38 to 127 mg/kg bw/day, 49 to 136 mg/kg bw/day and 21 to 122 mg/kg bw/day, for toddlers, children and adolescents, respectively. Anticipated exposure to caramel colour E 150d for adults ranges from 9 to 36 mg/kg bw/day at the mean, and from 26 to 101 mg/kg bw/day at the high level. For the elderly, exposures range from 6 to 22 mg/kg bw/day at the mean and from 19 to 60 mg/kg bw/day at the 95th percentile. Compared to the previous ANS Panel opinion exposures for children are at least 6 times lower at the mean and between 3 and 11 times lower at the high level. Current exposures for adults are around 2 to 10 times lower at the mean and up to 14 times lower at the high level, than the estimated exposures from the previous ANS Panel opinion.

For caramel colour E 150d, salt, spices, soups and sauces are the main contributing food category for toddlers, children, adults and the elderly (> 5 % in all surveys). Non-alcoholic beverages contribute to > 5% in all surveys for children, adolescents and adults. Dairy products also are contributing to > 5% in all surveys for toddlers and the elderly. In the previous ANS Panel opinion, soft drinks, confectionary and fine bakery wares were the main contributing food categories. For adults, confectionary and soft drinks were the main contributors to the total mean exposure in the previous estimates (EFSA, 2011a). Newly submitted reported use levels are much lower than those used in the previous ANS Panel opinion (lower levels by factor 12 to 15) may explained that confectionary is no more a main contributing food group.

The combined mean exposures to the four caramel colours range from 19 to 105 mg/kg bw/day for toddlers, from 31 to 83 mg/kg bw/day for children, from 12 to 56 mg/kg bw/day for adolescents and from 15 to 57 mg/kg bw/day for adults. At high levels, anticipated combined exposures range from 73 to 158 mg/kg bw/day for toddlers, from 68 to 160 mg/kg bw/day for children, from 28 to 144 mg/kg bw/day for adolescents and from 41 to 165 mg/kg bw/day for adults. The estimated exposures for the elderly are a bit lower with a mean combined intake ranging from 9 to 35 mg/kg bw/day and from 24 to 87 mg/kg bw/day at the 95th percentile. Compared to the previous ANS Panel opinion, current exposures for children are between 2 to 12 times lower at the mean and between 3 to 12 times lower at the high level. Current exposures for adults are around 3 to 13 times lower than the estimated exposures from previous ANS Panel opinion both at the mean and at the high level.

The main contributors to the combined mean exposure to caramel colours E 150a, E 150b, E 150c and E 150d are dairy products and salt, spices, soups and sauces for toddlers. The main contributors for children are salt, spices, soups and sauces, non-alcoholic beverages as well as edible ices. Non-alcoholic beverages contribute also to > 5 % in all surveys for children. Alcoholic beverages are the main contributors for adults and the elderly. For adults, salt, spices, soups and sauces contribute also for > 5% in all surveys. In the previous ANS Panel opinion, the main contributing food categories for children and adults were non-alcoholic beverages and confectionary. Beer and cider were the third greatest contributing food category for adults.

The current total mean and high level anticipated dietary exposure to caramel colour E 150a is below the group ADI of 300 mg/kg bw/day for all population groups at both mean and high exposure level while in the previous opinion of the ANS Panel (EFSA, 2011a), the estimated total mean and high (95th percentile) dietary exposures to caramel colour E 150a were above the ADI for children at the upper end of the ranges, as well as for adults for high exposures (97.5th percentile).

The refined estimated dietary exposure to caramel colour E 150c is below the ADI of 100 mg/kg bw/day at the mean for all population groups, while previously the upper end of the range of the mean anticipated exposure of children was above the ADI. At the high level of exposure, the ADI is still slightly exceeded at the upper end of the range estimates for toddlers and the upper end of the range estimates for adults exceed the ADI by 50%. In the previous assessment, the total estimated high intakes (95/97.5th percentile) of caramel colour E 150c were above the ADI for both children and adults.

For toddlers, the ADI is exceeded in one country at the high level of exposure (Appendix C), due to desserts, bakery wares and soups and sauces. In the previous ANS Panel opinion, children exceeded the ADI with the same main contributing food groups. It should be noted that the use levels used in the present estimate are the same as used previously for desserts while use levels in bakery wares were approximately half of previous values and those in sauces, soups, spices and seasonings were generally lower by a factor of 10.

For adults, the ADI is exceeded at the high levels (95th percentile) in 5 countries out of 15 (Appendix C). The exceedance is due to alcoholic beverages which is the main food category contributing to total mean exposure to caramel colour E 150c. It should be noted that the newly submitted use levels are lower for beer and cider but for spirit drinks and other alcoholic drinks (including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with < 15% of alcohol), the use levels used are now far higher than the ones used in the previous ANS Panel opinion for caramel colour E 150c (by a factor up to 50 times in spirits). No use levels were provided for some of the alcoholic beverages (aromatised wines, aromatised wines-based drinks) and MPLs from the Codex Alimentarius were used (as described in the rules defined by the ANS Panel). These MPLs are also higher than the use levels from the previous ANS Panel opinion (EFSA, 2011a).

For caramel colour E 150d, the refined estimated dietary exposure is below the group ADI at the mean as well as at the high level for all populations. In the previous estimates, adults were exceeding the group ADI at the high level and children at the upper end of the range of exposures at both mean and high level.

The combined exposure to caramel colours E 150a, E 150b, E 150c and E 150d both at the mean and at the high level are below the group ADI of 300 mg/kg bw/day for all population groups. In the previous opinion of the ANS Panel, mean and high level of anticipated intake for children was above 300 mg/kg bw/day at the upper end of the range; for adults, high level anticipated exposure was above the group ADI.

Table 12: Overview of exceedance of group or individual ADI in the present refined assessment of caramel colours

Caramel colour	Toddlers		Children		Adolescents		Adults		The elderly	
	mean	high level	mean	high level	mean	high level	mean	high level	mean	high level
E 150a	< group ADI		< group ADI		< group ADI		< group ADI		< group ADI	
E 150c	< individual ADI	> individual ADI	< individual ADI		< individual ADI		< individual ADI	> individual ADI	< individual ADI	
E 150d	< group ADI		< group ADI		< group ADI		< group ADI		< group ADI	
Combined exposure	< group ADI		< group ADI		< group ADI		< group ADI		< group ADI	

The exposure estimates of the current refined assessment are considerably lower than those of the previous ANS Panel opinion published in 2011. This is due both to the consumption data and to the occurrence data used. This refined exposure estimate is based on more consumption surveys for adults allowing a range of exposure estimates. No summary statistics were used and consumption data were used at the individual level which permit to decrease the conservativeness of the exposure output. As far as possible, foods were selected at detailed level from the FoodEx nomenclature. For example, non-alcoholic beverages which may contain caramel colours (cola-type beverages) were differentiated from other soft drinks and different use levels were applied for cola-type drinks and other soft drinks; this contributed to reducing the current exposure estimates. With respect to the previously reported use levels, lower levels as described in Appendix B, were provided for several food categories by food

industry (dairy products, sauces, soups and broths, beer, fine bakery wares, confectionary, fish and meat products, seasonings and condiments, vinegar), which also accounts for a major reduction of the total exposure.

As discussed before, several sources of uncertainty affect the exposure estimates. The Comprehensive Database gathers food consumption data from dietary surveys conducted in several Member States and collected through different methodologies, thus harmonisation of all databases in one results in loss of detailed information. Information on how representative the products are regarding use levels in the European market (market share data for European countries), and more occurrence data (monitoring data as well as usage data coming from more food industries) on the food categories could allow more refinements.

6. Uncertainty analysis

According to the guidance provided by the EFSA opinion (EFSA, 2006), the following sources of uncertainties have been considered. These were already presented and discussed in the sections above and are summarised below:

Assessment objective

The objective of the assessment was clearly specified in the terms of reference. EFSA carried out a refined exposure assessment using the FoodEx system and excluding non relevant subgroups from intake calculations.

- ***Input data***

  - Food consumption data: the data used for the exposure estimates were data reported at the individual level in several different dietary surveys which applied different methodologies. Under-reporting and/or misreporting often represent a bias in dietary surveys.

  - Food nomenclature: the food nomenclatures used in the dietary surveys considered and then the FoodEx nomenclature used in the Comprehensive Database are different from the Food Classification System developed for the definition of food additives uses in the Commission Regulation (EU) N° 1129/2011. Therefore, linking between different food nomenclatures leads to uncertainties.

  - Reported use levels: the estimates calculated are considered as being conservative because they are based on the assumption that all products within a given food category contain the caramel colours at the maximum reported use level. Typical use levels were used on a case by case basis when more information on the representativeness of use levels was made available.

Table 13: Qualitative evaluation of influence of uncertainties

Sources of uncertainties	Direction [(a)]
Consumption data: different methodologies / representativeness / under reporting / misreporting / no portion size standard	+/-
Extrapolation from food consumption survey of few days to estimate chronic exposure	+
Linkage between reported use levels and food items in the consumption database: uncertainties on which precise types of food the use levels refer.	+/-
Occurrence data: maximum reported use levels within a food category, exposure calculations based on the maximum reported use levels (use of typical use levels when available on a case by case basis)	+
Exposure model: uncertainty in possible national differences in use levels of food categories, data set not fully representative of foods on the EU market	+/-
Combined exposure to all four caramel colours:	+/-

(a) +: uncertainty with potential to cause over-estimation of exposure;
-: uncertainty with potential to cause under-estimation of exposure.

EFSA considered the impact of the uncertainties in the exposure assessment to caramel colours and concluded that overall uncertainty should lead to an overestimation of the calculated exposure estimates.

CONCLUSIONS

The current exposure estimates differ considerably from those of the previous opinion of the ANS Panel in 2011 (EFSA, 2011a). For caramel colour E 150a, the present estimates are 5 to 20 times lower compared to the earlier exposure estimates. For caramel colour E 150c, the current estimates are up to 5 times lower at the mean and from 2 to 10 times lower at the high levels for both children and adults. The mean exposure estimate for caramel colour E 150d is lower by a factor of 6 for children, and up to 10 times lower for adults; high level exposure estimates are up to 14 times lower. Compared with the previous ANS Panel opinion the combined exposure to all four caramel colours is lower by a factor of 3 to 13 for children and adults.

These differences in the outcomes of the exposure estimates are due to the new consumption data used and a refined selection of food items within the FoodEx nomenclature as well as to lower use levels provided by industry which represent use levels in products ready to be consumed.

EFSA concluded that the mean dietary exposure for the three populations of European children (toddlers, children and adolescents) ranges from 6 to 45 mg/kg bw/day for caramel colour E 150a, from 9 to 60 mg/kg bw/day for caramel colour E 150c and from 8 to 86 mg/kg bw/day for caramel colour E 150d. At the 95th percentile, estimates range from 16 to 81 mg/kg bw/day for caramel colour E 150a, from 20 to 106 mg/kg bw/day for caramel colour E 150c, and from 21 to 136 mg/kg bw/day for caramel colour E 150d.

For adults and the elderly, the anticipated dietary exposure for caramel colour E 150a gives a mean range through all European countries, of 4 to 18 mg/kg bw/day and of 13 to 42 mg/kg bw/day at the 95th percentile. For caramel colour E 150c, the mean ranges from 6 to 43 mg/kg bw/day and the 95th percentile ranges from 14 to 151 mg/kg bw/day. For caramel colour E 150d, the mean ranges from 6 to 36 mg/kg bw/day and the 95th percentile ranges from 19 to 101 mg/kg bw/day.

The anticipated combined mean exposures to the four caramel colours range from 12 to 105 mg/kg bw/day for toddlers, children, adolescents and adults, and between 28 and

165 mg/kg bw/day at the 95th percentile. For the elderly, the combined exposure to caramel colours E 150a, E 150b, E 150c and E 150d ranges from 9 to 35 mg/kg bw/day at the mean and from 24 to 87 mg/kg bw/day at the 95th percentile.

Based upon the above estimates, it is concluded that the ADI might be exceeded for caramel colour E 150c at the upper end of the range of high level exposure estimates for toddlers and adults. The combined exposure estimates of the four caramel colours do not exceed the group ADI for any population group.

DOCUMENTATION PROVIDED TO EFSA

1. FoodDrinkEurope (Europe Food and Drink Industry), 2012. FoodDrinkEurope's compilation on usage data on caramels colours. (FoodDrinkEurope's 2009 compilation of concentration data with 2011-2012 updates, February 2012)

2. FoodDrinkEurope (Europe Food and Drink Industry), EUTECA (European Technical Caramel Association), letters to the European Commission, September and October 2012.

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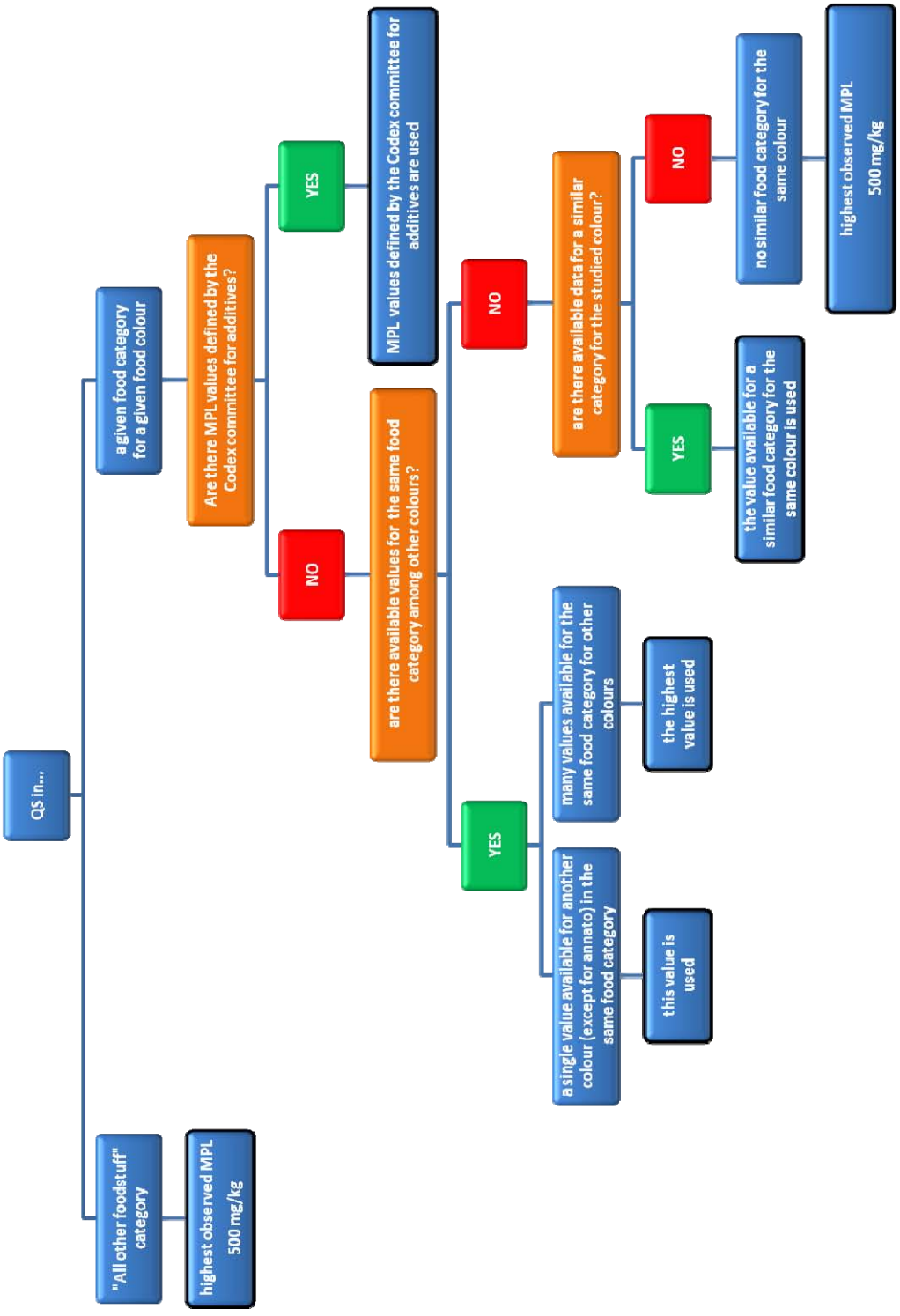
APPENDICES

A. RULES DEFINED BY THE PANEL TO DEAL WITH QUANTUM SATIS (QS) AUTHORISATION, USAGE DATA OR OBSERVED ANALYTICAL DATA FOR ALL REGULATED FOOD ADDITIVES TO BE RE-EVALUATED

Figure 1: Rules defined by the Panel to deal with usage data or observed analytical data for all regulated food additives to be re-evaluated and procedures for estimating intakes using these rules.

Figure 2: Rules defined by the Panel to deal with quantum satis (QS) authorisation



B. SUMMARY OF USE LEVELS (MG/KG) OF CARAMEL COLOURS (E 150A, E 150C AND E 150D) USED IN THE REFINED EXPOSURE ASSESSMENT

Cat N°	Foods	E Number / Group	Restrictions /exception	Caramel colour E 150a				Caramel colour E 150c					Caramel colour E 150d				
				FDE*	QS rules **	used levels	2011 Opinion levels	FDE	Codex MPLs ***	QS rules	used levels	2011 Opinion levels	FDE	Codex MPLs	QS rules	used levels	2011 Opinion levels
1.4	**Flavoured fermented milk products including heat treated products**	Group II		750		750	15 000	60			60	5120	60			60	1000
1.5	**Dehydrated milk as defined by Directive 2001/114/EC**	Group II	except unflavoured products	570		570	-	60			60	-	570			570	-
1.6.3	**Other creams**	Group II	only flavoured creams	570		570	-	60			60	-	570			570	-
1.7.1	**Unripened cheese excluding products falling in category 16**	Group II	only flavoured unripened cheese	570		570	-	570			570	-	570			570	-
1.7.3	**Edible cheese rind**	Group II			100	100	100		50 000		50 000	100		50 000		50 000	100
1.7.4	**Whey cheese**	Group II		570		570	-	570			570	-	570			570	-
1.7.5	**Processed cheese**	Group II	only flavoured processed cheese	570	100	570	100	570			570	-	570			570	-
1.7.6	**Cheese products (excluding products falling in category 16)**	Group II	only flavoured unripened products	570		570	100	570			570	-	570			570	-
1.8	**Dairy analogues, including beverage whiteners**	Group II			5	5	-		1000		1000	-		1000		1000	-
3	**Edible ices**	Group II		1990		1990	5000		1000		1000	1360	5200			5200	5200
4.2.1	**Dried fruit and vegetables**	E 150a-d	only preserves of red fruit		200	200	200			200	200	200			200	200	200
4.2.2	**Fruit and vegetables in vinegar, oil, or brine**	E 150a-d	only preserves of red fruit	-	200	200	200		200		200	200		7500		7500	200
4.2.2	**Fruit and vegetables in vinegar, oil, or brine**	E 150a-d	only vegetables (excluding olives)	-	200	200	500		500		500	500		7500		7500	500
4.2.3	**Canned or bottled fruit and vegetables**	E 150a-d	only preserves of red fruit		200	200	200		200		200	200		7500		7500	200
4.2.4.1	**Fruit and vegetable preparations excluding compote**	Group II	only mostarda di frutta		200	200	200		7500		7500	2050		7500		7500	200
4.2.4.1	**Fruit and vegetable preparations excluding compote**	E 150a-d	only preserves of red fruit		200	200	200		7500		7500	200		7500		7500	200
4.2.5.2	**Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EEC**	E 150a-d	except chestnut puree	4000		4000	4000	400			400	100	400			400	100
4.2.5.3	**Other similar fruit or vegetable spreads**	Group II	except *crème de pruneaux*	4000		4000	4000	400			400	100	400			400	100

Cat N°	Foods	E Number / Group	Restrictions /exception	Caramel colour E 150a				Caramel colour E 150c					Caramel colour E 150d				
				FDE*	QS rules **	used levels	2011 Opinion levels	FDE	Codex MPLs ***	QS rules	used levels	2011 Opinion levels	FDE	Codex MPLs	QS rules	used levels	2011 Opinion levels
5.2	**Other confectionery including breath refreshening microsweets**	Group II		7000		7000	10 000	10 000			10 000	8000	25 000			25 000	300 000
5.3	**Chewing gum**	Group II			10 000	10 000	10 000		20 000		20 000	8000		20 000		20 000	300 000
5.4	**Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4**	Group II		297		297	40	6050			6050	3400	14 000			14 000	500
6.3	**Breakfast cereals**	Group II	only breakfast cereals other than extruded, puffed and/or fruit flavoured breakfast cereals	2200		2200	-	3000			3000	-	41			41	-
6.3	**Breakfast cereals**	E 150c	only extruded puffed and or fruit flavoured breakfast cereals	2200		2200	10 010	3000			3000	2040	41			41	500
6.5	**Noodles**	Group II			500	500		510			510		510			510	
6.6	**Batters**	Group II															
6.7	**Pre-cooked or processed cereals**	Group II															
7.1.	**Bread and rolls**	E 150a-d	only Malt bread	5000		5000	30 000	2000			2000	2040	5000			5000	5000
7.2	**Fine bakery wares**	Group II		4900		4900	15 000	5500			5500	11 500	2500			2500	5000
8.1.2	**Meat preparations as defined by Regulation (EC) No 853/2004**	E 150a-d	only *breakfast sausages* with a minimum cereal content of 6 % and *burger meat* with a minimum vegetable and/or cereal content of 4 % mixed within the meat; In these products, the meat is minced in such a way so that the muscle and fat tissue are completely dispersed, so that fibre makes an emulsion with the fat, giving those products their typical appearance	-	100	100	100	5000			5000	100	2000			2000	100
8.2.1	**Non heat treated processed meat**	E 150a-d	only sausages		100	100	8000	5000			5000	5000	2000			2000	5000
8.2.2	**Heat treated processed meat**	E 150a-d	only sausages, patés and terrines		100	100	8000	5000			5000	5000	2000			2000	5000
8.2.3	**Casings and coatings and decorations for meat**	Group II	except edible external coating of pasturmas		500	500	500	5000			5000	500	2000			2000	500
9.2.	**Processed fish and fishery products including molluscs and crustaceans**	Group II	only surimi and similar products and salmon substitutes.		500	500	500	5000			5000	500	2000			2000	500

Cat N°	Foods	E Number / Group	Restrictions /exception	Caramel colour E 150a				Caramel colour E 150c					Caramel colour E 150d				
				FDE*	QS rules **	used levels	2011 Opinion levels	FDE	Codex MPLs ***	QS rules	used levels	2011 Opinion levels	FDE	Codex MPLs	QS rules	used levels	2011 Opinion levels
9.2.	**Processed fish and fishery products including molluscs and crustaceans**	E 150a-d	only fish paste and crustacean paste		100	100	100	5000			5000	100	2000			2000	100
9.2.	**Processed fish and fishery products including molluscs and crustaceans**	E 150a-d	only precooked crustacean		250	250	250	5000			5000	250	2000			2000	250
9.3	**Fish roe**	Group II	except Sturgeons' eggs (Caviar)		300	300	300	5000			5000	300	2000			2000	300
12.2.2	**Seasonings and condiments**	Group II	only seasonings, for example curry powder, tandoori	21 000		21 000	100 000	5000			5000	100 000	20 000			20 000	20 000
12.3	**Vinegars**	E 150a-d		-	500	500	6000	5000			5000	100 000		50 000		50 000	100 000
12.4	**Mustard**	Group II		25 000	300	25 000	300		50 000		50 000	2000		50 000		50000	300
12.5	**Soups and broths**	Group II		1332		1332	50 000	3000			3000	3000	3000			3000	4000
12.6	**Sauces**	Group II	excluding tomato-based sauces	500		500	100 000	10000			10 000	100 000	10 000			10 000	20 000
12.7	**Salads and savoury based sandwich spreads**	Group II		5		5	-	5			5	-	5			5	-
12.9	**Protein products, excluding products covered in category 1.8**	Group II		16 000		16 000	40 000			10000	10 000	10 000			1000	1000	2000
13.2	**Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)**	Group II	Products in this category can also use additives that are allowed in the corresponding food counterparts categories		50	50	50	9500			9500	9500	615			615	1000
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 II		2500		2500	7000		20 000		20 000	50		20 000		20 000	50
13.4	**Foods suitable for people intolerant to gluten as defined by Regulation (EC) 41/2009**	Group II	Products in this category can also use additives that are allowed in the corresponding food counterparts categories. In addition, all additives in the gluten containing counterparts are authorised.		500	500	-			500	500	-			500	500	-
14.1.4	**Flavoured drinks**	Group II	excluding chocolate milk; malt products/ FOR COLAS	1500		1500	10 000	500			500	1360	4950			4950	5000
14.1.4	**Flavoured drinks**	Group II	excluding chocolate milk; malt	1500		1500		500			500		2000			2000	

Cat N°	Foods	E Number / Group	Restrictions /exception	Caramel colour E 150a				Caramel colour E 150c					Caramel colour E 150d				
				FDE*	QS rules **	used levels	2011 Opinion levels	FDE	Codex MPLs ***	QS rules	used levels	2011 Opinion levels	FDE	Codex MPLs	QS rules	used levels	2011 Opinion levels
			products														
14.2.1	**Beer and malt beverages**	E 150a-d	only beer	1000		1000	10 000	6000			6000	8000	0			0	500
14.2.3	**Cider and perry**	Group II	excluding *cidre bouché*		200	200	6000	60			60	680	70			70	600
14.2.3	**Cider and perry**	E 150a-d	only *cidre bouché*		200	200	2000	60			60	2040	70			70	500
14.2.4	**Fruit wine and made wine**	Group II			200	200	6000		1000		1000	680	560			560	560
14.2.5	**Mead**	Group II			200	200			1000		1000			1000		1000	
14.2.6	**Spirit drinks as defined in Regulation (EC) No 110/2008**	Group II	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.	15 000		15 000	5000	10 000			10 000	680	10 000			10 000	5000
14.2.6	**Spirit drinks as defined in Regulation (EC) No 110/2008**	E 150a-d	except: fruit spirits, spirits (preceded by the name of the fruit) obtained by maceration and distillation, London Gin, Sambuca, Maraschino, Marrasquino or Maraskino and Mistrà. Whisky, whiskey can only contain E 150a.	15 000		15 000	15 000	10000			10 000	200	10 000			10 000	5000
14.2.7.1	**Aromatised wines**	Group II	Except *americano, bitter vino*	-	200	200	10 000		50 000		50 000	680		50 000		50 000	200
14.2.7.1	**Aromatised wines**	E 150a-d		-	200	200	5000		50 000		50 000	680		50 000		50 000	5000
14.2.7.1	**Aromatised wines**	E 150a-d	only *americano, bitter vino*	-	100	100	5000		50 000		50 000	100		50 000		50 000	1000
14.2.7.2	**Aromatised wine-based drinks**	Group II	except *bitter soda, sangria, claria, zurra*		200	200	5000		50 000		50 000	680		50 000		50 000	5000
14.2.7.2	**Aromatised wine-based drinks**	E 150a-d	only *bitter soda*		100	100	100		50 000		50 000	100		50 000		50 000	100
14.2.7.3	**Aromatised wine-product cocktails**	Group II			200	200	10 000		50 000		50 000	680		50 000		50 000	200

Cat N°	Foods	E Number / Group	Restrictions /exception	Caramel colour E 150a				Caramel colour E 150c					Caramel colour E 150d				
				FDE*	QS rules **	used levels	2011 Opinion levels	FDE	Codex MPLs ***	QS rules	used levels	2011 Opinion levels	FDE	Codex MPLs	QS rules	used levels	2011 Opinion levels
14.2.8	**Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol**	Group II			200	200	30	4950			4950	30	4950			4950	30
15.1	**Potato, cereal, flour or starch-based snacks**	Group II		3000		3000	3000	3000			3000	2040	1490			1490	1000
15.2	**Processed nuts**	Group II		3000		3000	3000	3000			3000	2040	16			16	1000
16	**Desserts excluding products covered in category 1, 3 and 4**	Group II		2774		2774	15000	5120			5120	5120	5120			5120	1000
17.1	**Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms**	Group II			300	300	300		20 000		20 000	300		20 000		20 000	300
17.2	**Food supplements supplied in a liquid form**	Group II			100	100	15 000		20 000		20 000	100	1500			1500	620
17.3	**Food supplements supplied in a syrup-type or chewable form**	Group II			300	300	-		20 000		20 000	-		20 000		20 000	-

*Data from FoodDrinkEurope/EUTECA provided to EFSA between June and October 2012.
**Data from Quantum Satis rules (see Appendix A)
***Maximum Permitted Levels as mentioned in the Codex Alimentarius GSFA

C. SUMMARY OF TOTAL ESTIMATED EXPOSURE (USING MPLS AND USE LEVELS) PER AGE CLASS AND SURVEY*: MEAN AND HIGH LEVEL (MG/KG BW/DAY)

	E 150a		E 150c		E 150d		Combined exposure	
	Mean	High level	Mean	High level	Mean	High level	Mean	High level
Toddlers								
Belgium (Regional_Flanders)	44.6	-	59.7	-	85.6	-	105.3	-
Bulgaria (Nutrichild)	22.5	54.1	30.5	65.5	27.9	64.3	41.1	91.8
Finland (DIPP)	10.7	32.3	9.9	35.6	11.1	38.4	18.9	73.4
Germany (Donald 2006_2008)	12.9	34.3	23.6	58.6	22.3	62.1	35.9	88.6
Italy (INRAN_SCAI_2005_06)	16.2	-	19.8	-	19.5	-	28.5	-
The Netherlands (VCP_Kids)	39.9	78.5	53.2	106.3	58.2	126.5	77.5	158.4
Spain (enKid)	17.3	-	27.7	-	19.5	-	32.0	-
Children								
Belgium (Regional_Flanders)	39.3	80.7	48.0	91.6	62.1	135.9	80.9	160.3
Bulgaria (Nutrichild)	26.9	61.4	34.3	74.6	34.9	85.3	51.5	119.0
Czech Republic (SISP04)	32.4	70.7	32.0	69.5	41.2	98.5	58.1	129.3
Denmark (Danish Dietary Survey)	23.6	43.4	26.9	48.2	43.1	81.1	52.3	92.6
Finland (DIPP)	19.3	36.3	22.7	50.0	35.3	86.3	49.2	109.3
Finland (STRIP)	37.5	64.4	56.0	97.2	62.2	116.3	83.2	136.4
France (INCA 2)	29.1	54.6	40.5	73.4	39.0	76.9	56.1	104.5
Germany (Donald 2006_2008)	19.4	39.5	30.6	57.1	35.5	78.2	51.9	105.9
Greece (Regional_Crete)	19.3	42.0	22.9	51.2	19.2	49.2	31.1	69.3
Italy (INRAN_SCAI_2005_06)	15.5	37.2	19.9	43.1	20.3	50.9	31.4	68.0
Latvia (EFSA_TEST)	23.3	54.6	42.6	93.3	37.7	83.5	50.6	112.4
The Netherlands (VCP_Kids)	37.1	74.2	47.3	93.5	56.6	122.5	74.0	146.4
Spain (enKid)	18.0	44.9	28.9	62.7	25.0	61.4	38.7	82.4
Spain (Nut_Ink05)	17.2	35.6	30.6	63.2	26.8	66.7	40.0	80.9
Sweden (NFA)	31.8	62.1	43.8	82.3	55.3	115.2	75.6	144.5

	E 150a		E 150c		E 150d		Combined exposure	
	Mean	High level	Mean	High level	Mean	High level	Mean	High level
Adolescents								
Belgium (Diet_National_2004)	20.0	43.3	33.2	86.3	43.8	121.9	56.4	143.8
Cyprus (Childhealth)	6.4	16.5	9.4	20.3	8.2	20.7	12.1	27.8
Czech Republic (SISP04)	24.3	56.3	26.9	60.5	31.6	74.4	44.9	106.7
Denmark (Danish Dietary Survey)	18.4	37.8	20.7	47.3	31.1	66.5	39.4	82.6
France (INCA 2)	15.4	34.6	22.2	45.3	23.2	52.4	32.1	69.6
Germany (National_Nutrition_Survey_II)	15.4	45.0	29.1	73.3	32.8	92.3	43.3	125.5
Italy (INRAN_SCAI_2005_06)	11.1	36.0	11.5	28.8	17.0	50.8	23.0	61.1
Latvia (EFSA_TEST)	15.0	36.4	27.9	58.3	24.6	52.0	33.3	69.4
Spain (AESAN_FIAB)	10.4	22.3	15.2	34.2	15.9	40.9	24.0	52.1
Spain (enKid)	12.2	30.4	20.4	46.7	19.2	43.5	27.7	57.1
Spain (Nut_Ink05)	11.6	27.6	19.9	39.5	21.2	56.3	29.1	68.1
Sweden (NFA)	19.3	42.5	26.1	54.0	37.2	88.9	47.3	101.9

	E 150a		E 150c		E 150d		Combined exposure	
	Mean	High level	Mean	High level	Mean	High level	Mean	High level
Adults								
Belgium (Diet_National_2004)	15.5	37.9	35.9	104.5	35.6	100.6	50.9	139.1
Czech Republic (SISP04)	15.9	42.1	43.3	151.3	14.4	33.4	50.0	165.4
Denmark (Danish_Dietary_Survey)	14.4	33.7	26.4	75.5	19.8	47.2	37.7	90.4
Finland (FINDIET_2007)	7.7	23.0	16.7	60.4	12.7	39.2	23.8	76.7
France (INCA2)	10.3	24.1	25.1	74.0	23.6	72.6	31.8	85.8
Germany (National_Nutrition_Survey_II)	12.5	32.2	31.1	93.5	22.3	63.4	39.5	111.7
Hungary (National_Repr_Surv)	7.1	15.9	13.0	41.8	13.7	36.2	21.1	58.4
Ireland (NSIFCS)	12.9	33.0	38.3	139.3	15.6	41.0	44.8	147.9
Italy (INRAN_SCAI_2005_06)	6.4	19.0	9.6	27.4	9.1	26.0	15.1	41.4
Latvia (EFSA_TEST)	9.3	22.7	21.9	54.9	14.7	31.6	23.8	60.7
The Netherlands (DNFCS_2003)	17.9	40.8	41.0	137.3	36.1	99.9	57.4	148.2
Spain (AESAN)	8.8	25.1	17.4	62.0	16.0	52.3	27.7	84.7
Spain (AESAN_FIAB)	8.1	20.7	13.5	37.3	13.9	43.3	21.9	58.3
Sweden (Riksmaten_1997_98)	14.7	29.8	30.2	65.2	20.2	46.1	39.3	82.7
United Kingdom (NDNS)	12.3	29.0	38.9	134.3	24.3	70.1	46.1	145.2
The elderly								
Belgium (Diet_National_2004)	11.6	25.8	30.0	81.9	22.2	60.3	34.5	87.1
Denmark (Danish_Dietary_Survey)	12.4	31.7	25.8	68.2	14.8	43.3	34.0	83.2
Finland (FINDIET_2007)	4.8	13.6	7.9	24.4	7.6	22.0	12.1	35.7
France (INCA2)	7.7	18.9	18.8	52.0	15.9	45.4	22.7	58.7
Germany (National_Nutrition_Survey_II)	10.2	25.9	26.3	80.3	13.2	30.7	29.5	83.3
Hungary (National_Repr_Surv)	5.7	13.4	9.7	27.3	9.6	19.6	14.8	34.4
Italy (INRAN_SCAI_2005_06)	4.1	12.8	5.6	13.9	6.3	18.5	9.0	24.3

*The different methodologies of European dietary surveys included in the EFSA Comprehensive Database are fully described in the Guidance on the use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment (EFSA, 2011a). A summary is available p.11, Table 1 of the guidance.

GLOSSARY AND 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
EUTECA	European Technical Committee on Caramels
FCS	Food Categorisation System (food nomenclature) presented in the Commission Regulation (EU) N° 1129/2011
GSFA	Codex General Standard for Food Additives. Online Database available here: http://www.codexalimentarius.net/gsfaonline/index.html
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MPL	Maximum Permitted Level
QS	Quantum satis
SCF	Scientific Committee for Food
TemaNord	Nordic Council of Ministers

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EFSA on caramel colours: Consumer exposure lower than previously estimated

By Nathan Gray+, 19-Dec-2012

Related topics: Flavours and colours, Legislation

Consumer exposure to three caramel colours used in a variety of food and drink applications is 'considerably lower' than a 2011 scientific opinion published by EFSA suggested, says the Authority.

The European Food Safety Authority (EFSA) has revised its estimate of consumer exposure to three caramel colours (E 150a, E 150c, E 150d) used in a variety of foods and beverages, after new data on industry usage and consumption helped the scientific risk assessor to come to a better estimate.

Using new data on the levels of three caramel colours (E 150a, E 150c, E 150d) as they are used in food and drinks as well as new consumption data, EFSA has now concluded that consumer exposure to these colours *"is considerably lower than that expressed in the Authority's 2011 scientific opinion."*

"In that opinion, the Panel concluded that the anticipated dietary exposure of child and adult populations may exceed the Acceptable Daily Intake (ADI) for caramel colours E 150a, E 150c and E 150d, but exposure estimates to E 150b were below the ADI," said EFSA, adding that the new data has allowed it to revise its findings.

"The estimated combined exposure to the four caramel colours (E 150a, E 150b, E 150c, E 150d) are considerably lower and the group ADI of 300 mg/kg bw/day is not exceeded for any population group in the current review."

Caramel exposure

In its 2011 opinion, EFSA's Scientific Panel on Additives and Nutrient Sources Added to Food (ANS Panel) carried out a total re-evaluation of the safety of the three caramel colours plus one other (E 150b); and established acceptable daily intake limits (ADIs) for their use in food.

At the time the ANS Panel said that given their similar chemical properties and uses in food, a group ADI of 300 milligrams per kilogram of body weight per day (mg/kg bw/day) for combined exposure to all four caramel colours should be set.

Based on the limited information available at the time, that 2011 opinion went on to say that it was possible that the use of caramel colours in foods may lead to exposures in excess of the ADIs.

However, in its new statement, EFSA has refined its estimate of likely exposure to caramel colours in food based on new data.

EFSA said the new 2012 data has been provided by industry information on usage of the colours in products, in conjunction with consumption data from the EFSA Comprehensive European Food Consumption Database.

"The results of the current exposure assessment for caramel colours E 150a, E 150c and E 150d and combined exposure to the four caramel colours are considerably lower than those of the original opinion," said the updated EFSA opinion.