European Food Safety Authority

EFSA Journal 2014;12(1):3492

SCIENTIFIC OPINION

Scientific Opinion on the reconsideration of the ADI and a refined exposure assessment of β-apo-8′-carotenal (E 160e)[1]

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

This scientific opinion, published on 24 March 2014, replaces the earlier version published on 22 January 2014.

ABSTRACT

The Panel on Food Additives and Nutrient Sources added to Food (ANS) has previously provided a scientific opinion re-evaluating the safety of β-apo-8′-carotenal (E 160e) as a food additive in the EU and establishing an acceptable daily intake (ADI) of 0.05 mg/kg body weight (bw)/day (EFSA ANS Panel, 2012). Following a request by the European Commission, the ANS Panel was asked to consider newly submitted information on the interpretation of the 13-week study in rats used as a basis to establish the ADI, to clarify its impact on that ADI and to carry out the refined exposure assessment of β-apo-8′-carotenal. The new information comprised an evaluation of all of the original kidney section slides from the 13-week toxicological study under improved visualisation conditions. The ANS Panel has considered that the supplementary information provided by the Commission and the present toxicological database on β-apo-8′-carotenal provides a basis to revise the established ADI and concluded that, based on the NOAEL of 30 mg/kg bw/day from the 13-week study in rats and an uncertainty factor of 100, a new ADI for β-apo-8′-carotenal of 0.3 mg/kg bw/day can be established. The Panel concluded that using data provided by the food industry, which are based only on a limited number of regulated categories, the reported uses and use levels of β-apo-8'-carotenal (E 160e) would not be of safety concern.

KEY WORDS

β-apo-8′-carotenal, E 160e, CAS Registry Number 1107-26-2, food colour, refined exposure, ADI

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[1] On request from the European Commission, Question No EFSA-Q-2012-01001, adopted on 03 December 2013.

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group B on Food Additives and Nutrient Sources added to Food: Fernando Aguilar, Riccardo Crebelli, Birgit Dusemund, David Gott, Torben Hallas-Møller, Jürgen König, Oliver Lindtner, Daniel Marzin, Inge Meyland, Alicja Mortensen, Agneta Oskarsson, Iona Pratt (deceased), Paul Tobback, Ine Waalkens-Berendsen and Ruud Woutersen for the preparatory work on this scientific opinion and EFSA staff: Anna Christodoulidou, Petra Gergelova and Stavroula Tasiopoulou for the support provided to this scientific opinion.

* Minor changes of editorial nature were made. The changes do not affect the contents of this report. To avoid confusion, the original version of the opinion has been removed from the website, but is available on request, as is a version showing all the changes made.

Suggested citation: EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2014. Scientific Opinion on the reconsideration of the ADI and a refined exposure assessment of β-apo-8′-carotenal (E160e). EFSA Journal 2014;12(1):3492, 30 pp. doi:10.2903/j.efsa.2014.3492

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

SUMMARY

Following a request from the European Commission (EC) to the European Food Safety Authority (EFSA), the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) delivered a scientific opinion reevaluating the safety of β-apo-8′-carotenal (E 160e) when used as a food colour (EFSA ANS Panel, 2012). In this re-evaluation, the ANS Panel used a 13-week study in rats to establish an acceptable daily intake (ADI) of 0.05 mg/kg body weight (bw)/day for β-apo-8′-carotenal (E 160e).

After the publication of the EFSA opinion, the European Commission received new information concerning the interpretation of kidney data from this 13-week study in rats and considered that EFSA implemented new methodology in its exposure assessment. Therefore, the European Commission requested EFSA to reconsider the established ADI and to refine the exposure assessment of its previous opinion.

The Panel was provided with supplementary information on the evaluation of the significance of kidney changes (Hard, 2012), previously observed by Edwards et al (2007) and Perry and Shearer (2008). The Panel evaluated the new report (Hard, 2012) reviewing the significance of eosinophilic droplets in the kidneys of rats of both sexes observed at all dose levels of β-apo-8'-carotenal active ingredient/kg bw/day. The material was most prominent in the cortical tubules of female rats exposed to 100 mg/kg bw/day. Hard (2012) suggested that it was very likely that the eosinophilic material represented accumulation of the test compound or a derivative during normal renal processing. The persistence of a reduced amount of the accumulating material in proximal convoluted tubule cells of the kidneys at the end of the 4-week recovery period indicated that the material was eliminated, but at a relatively slow rate (Hard, 2012). At the high dose of 100 mg/kg bw/day, a rare condition of cell detachments was suspected, accompanied by very occasional mitotic figures, which suggested that the normal ability of the proximal tubule to repair proximal convoluted tubule cells affected by the accumulated material might have marginally been exceeded at this dose. Based on these observations, the author concluded that 30 mg/kg bw/day represented a no observed adverse effect level (NOAEL), since no microscopic evidence of tubule injury was observed at this dose. The Panel agreed with this conclusion.

The Panel concluded that based on the NOAEL of 30 mg/kg bw/day from the 13-week study in rats, in which tubular cell injury was observed at 100 mg/kg bw/day, and using an uncertainty factor of 100, an ADI for β-apo-8'-carotenal of 0.3 mg/kg bw/day was established. The Panel considered an uncertainty factor of 100 as sufficient, not needing an extra adjusting factor due to the pivotal study being a subchronic study (and not a chronic study), given the fact that tubular injury was not observed in the two-year study at 40 mg/kg bw/day, the single dose tested.

Scenarios used for the exposure assessment based on the MPLs or use levels in reported food categories combined with the MPLs for other categories led to an exceedance of the ADI up to 10-20 fold in all population groups, both at mean and high level exposure.

However, a further refined exposure scenario was based only on the limited number of categories where industry reported use levels and analytical data. Exposure estimates using this scenario were below the ADI at the mean level for all population groups. At high level of exposure, the ADI was exceeded for toddlers and children, and the exposure for adolescents was at about the ADI. The Panel considered that this high level exposure estimate was still conservative and concluded that these exceedances are unlikely to occur. The Panel concluded that the uses and use levels of β-apo-8'-carotenal (E 160e), as reported by the food industry, would not be of safety concern.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Following a request from the European Commission to the European Food Safety Authority (EFSA), the Panel on Food Additives and Nutrient Sources added to Food was asked to deliver a scientific opinion reevaluating the safety of β-apo-8'-carotenal (E 160e) as a food additive. The European Food Safety Authority has re-evaluated the safety of β-apo-8'-carotenal (E 160e) in 2012 (EFSA ANS Panel, 2012). In this re-evaluation EFSA established an ADI for β-apo-8'-carotenal (E 160e) at 0.05 mg/kg bw/day.

After the publication of the EFSA opinion, the European Commission received new information concerning the interpretation of kidney data from a 13-week study in rats and considered the fact that meanwhile EFSA implemented new methodology in its exposure assessment. Therefore, the European Commission requested EFSA to reconsider the established ADI and to refine the exposure assessment of its previous opinion.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Article 29 (1)(a) of Regulation (EC) No 178/2002, the European Commission asked EFSA to consider newly submitted information on the interpretation of the 13-week study in rats used as a basis to derive the ADI, to clarify its impact on the established ADI and to carry out the refined exposure assessment of β-apo-8'-carotenal.

EVALUATION

1. Introduction

Following a request from the European Commission (EC) to the European Food Safety Authority (EFSA), the Panel on Food Additives and Nutrient Sources added to Food (ANS) delivered a scientific opinion reevaluating the safety of β-apo-8′-carotenal (E 160e) when used as a food colour.

In this re-evaluation (EFSA ANS Panel, 2012), a subchronic 13-week study with β-apo-8′-carotenal 10 % WS/N in rats, given doses of 0, 10, 30 and 100 β-apo-8′-carotenal active ingredient/kg body weight (bw)/day (Edwards et al., 2007; Perry and Shearer, 2008), was used to establish an acceptable daily intake (ADI). Histopathologically, administration of β-apo-8′-carotenal 10 % WS/N in the diet was associated with eosinophilic droplets in the kidneys of both sexes at 10 mg β-apo-8′-carotenal active ingredient/kg bw/day and above; multinucleate hepatocytes (MNH) in the liver of females at 30 mg β-apo-8′-carotenal active ingredient/kg bw/day and above; and increased numbers of inflammatory cell foci in the liver of females at 100 mg β-apo-8′-carotenal active ingredient/kg bw/day. The Panel concluded that the presence of MNH as observed in this study was reversible and not adverse. The Panel, however, noted that the finding of eosinophilic droplets in the kidney of all exposed groups suggests the kidney as the target organ.

The Panel evaluated the data on the eosinophilic droplets in the kidneys of both sexes at 10 mg β-apo-8′-carotenal active ingredient/kg bw/day and above. From these data, the Panel concluded that 10 mg/kg bw/day is a lowest observed adverse effect level (LOAEL) for this effect, and established an ADI of 0.05 mg/kg bw/day for β-apo-8′-carotenal (E 160e).

After the publication of the EFSA opinion, the EC received new information concerning the interpretation of the kidney data from this 13-week study in rats and considered that EFSA implemented new methodology in its exposure assessment. Therefore, the EC requested EFSA to reconsider the established ADI and to refine the exposure assessment of its previous opinion.

2. Evaluation of new toxicological data

2.1. Re-examination of the renal histological changes occurring in the 13-week study in rats

The Panel was provided with supplementary information on the evaluation of the significance of kidney changes (Hard, 2012) previously observed by Edwards et al. (2007) and Perry and Shearer (2008). Hard (2012), an experienced expert in renal pathology, re-examined the kidney slides under improved visualisation conditions using an Olympus BX41 microscope, under both brightfield and ultraviolet using objectives ranging from 4- 40× magnification.

The main change associated with β-apo-8′-carotenal exposure appeared to be the presence of ill-defined clumps of droplets of eosinophilic material in the cytoplasm of the proximal convoluted tubule cells of the kidneys. This change was particularly evident in the female rats, ranging from minimal involvement of cortical tubules at the low dose (10 mg/kg bw/day) to virtually all cortical tubules (mild to moderate in severity) at the high dose (100 mg/kg bw/day). The report suggested that the eosinophilic material represented accumulation of the test material, which caused no apparent injury to the tubule cells, except in the high-dose animals. In these animals some slight changes were reported (cell detachments and very occasional mitotic figures), which were ascribed to the marginally exceeded ability of the tubules to deal with the accumulated material. Therefore, the report concluded that 30 mg/kg bw/day represented a no observed adverse effect level (NOAEL), since no microscopic evidence of tubule injury was observed at this dose (Hard, 2012). The Panel agreed with this conclusion, but noted that no analysis of the accumulated material has been provided to demonstrate that it was related to the test material.

3. Exposure assessment of β-apo-8′-carotenal (E 160e)

In its 2012 opinion, the ANS Panel had evaluated the exposure to β-apo-8'-carotenal (E 160e) on the basis of the uses and use levels authorised in the legislation and the reported use levels, as provided by industry, and concluded that for exposure estimates at tier 3, the ADI of 0.05 mg/kg bw was reached at the mean, and exceeded at the 95thpercentile of exposure for adults, and both at the mean and the 95th/97.5th percentile for children (EFSA ANS Panel, 2012).

Table 1: Summary of anticipated exposure to β-apo-8'-carotenal (E 160e) in children and the adult population (EFSA ANS Panel, 2012)

	Adult UK population (> 18 years old) (mg/kg bw/day)	**Children UK and EXPOCHI population** (1-10 years old, 15.8-29 kg body weight) (mg/kg bw/day)
Tier 1. Budget method	8.1	13.1
Tier 2. Maximum permitted level		
• Mean exposure	0.9	0.5 – 3.4
• Exposure 95th or 97.5th percentile[(a)]	3.3	1.2 – 7.2
Tier 3. Maximum reported use levels		
• Mean exposure	0.05	0.02 – 0.22
• Exposure 95th or 97.5th percentile[(a)]	0.19	0.09 – 0.71

(a): For the UK population, estimates were based on the UNESDA report which gives the 97.5th percentile (Tennant, 2006).

For UK adults, the main contributors (> 10 %) to the total anticipated mean exposure to β-apo-8'-carotenal (E 160e) were non-alcoholic flavoured drinks (92 %), while for children, the main contributors were non-alcoholic flavoured drinks (50-91%) and fine bakery wares (11-50 %).

3.1. Maximum permitted levels of use of β-apo-8'-carotenal (E 160e)

Maximum permitted levels (MPLs) of β-apo-8'-carotenal (E 160e) have been defined in the Annex II of Regulation (EC) No 1333/2008[4] on food additives for use in foodstuffs.

Currently, β-apo-8'-carotenal (E 160e) is an authorised food colour in the EU with MPLs ranging from 50 to 500 mg/kg in foods. The use of β-apo-8'-carotenal (E 160e) is permitted in flavoured processed cheese, fish paste and crustacean paste, precooked crustacean and smoked fish, individually or in combination with other food colours.[5] β-Apo-8'-carotenal (E 160e) is also included in the Group III of food colours authorised with a combined maximum limit (Regulation (EC) No 1333/2008) (Table 2).

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

[5] Combinations with the following food colours are considered: E 100, E 102, E 104, E 110, E 120, E 122, E 124, E 129, E 142, E 151 and E 161b.

Table 2: MPLs of β-apo-8'-carotenal (E 160e) in foods according to the Annex II of Regulation (EC) No 1333/2008

FCS category number	Foods	Restrictions/exceptions	Maximum level (mg/l or mg/kg as appropriate)
1.4	Flavoured fermented milk products including heat-treated products		150
1.6.3	Other creams	only flavoured creams	150
1.7.1	Unripened cheese excluding products falling in category 16	only flavoured unripened cheese	150
1.7.3	Edible cheese rind		QS
1.7.5	Processed cheese	only flavoured processed cheese	100[(a)]
1.7.6	Cheese products (excluding products falling in category 16)	only flavoured unripened products	100
3	Edible ices		150
4.2.4.1	Fruit and vegetable preparations excluding compote	only mostarda di frutta	200
5.2.	Other confectionery including breath freshening microsweets	except candied fruit and vegetables	300
5.2.	Other confectionery including breath freshening microsweets	only candied fruit and vegetables	200
5.3.	Chewing gum		300
5.4.	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	only decorations, coatings and sauces, except fillings	500
5.4.	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	only fillings	300
6.6	Batters	only batters for coating	500
7.2.	Fine bakery wares		200
8.2.3	Casings and coatings and decorations for meat	only decorations and coatings except edible external coating of *pasturmas*	500
8.2.3	Casings and coatings and decorations for meat	only edible casings	QS
9.2.	Processed fish and fishery products including molluscs and crustaceans	only fish paste and crustacean paste	100[(b)]
9.2.	Processed fish and fishery products including molluscs and crustaceans	only surimi and similar products and salmon substitutes	500
9.2.	Processed fish and fishery products including molluscs and crustaceans	only precooked crustacean	250[(c)]
9.2	Processed fish and fishery products including molluscs and crustaceans	Only smoked fish	100[(d)]
9.3	Fish roe	except Sturgeons' eggs (Caviar)	300
12.2.2	Seasonings and condiments	only seasonings, for example curry powder, tandoori	500
12.4	Mustard		300
12.5	Soups and broths		50
12.6	Sauces	including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces	500

Table 2 : MPLs of β-apo-8'-carotenal (E 160e) in foods according to the Annex II of Regulation (EC) No 1333/2008 continued.

FCS category number	Foods	Restrictions/exceptions	Maximum level (mg/l or mg/kg as appropriate)
12.9	Protein products, excluding products covered in category 1.8	only meat and fish analogues based on vegetable proteins	100
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)		50
13.3	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)		50
14.1.4	Flavoured drinks	excluding chocolate milk and malt products	100
14.2.3	Cider and perry	excluding *cidre bouché*	200
14.2.4	Fruit wine and made wine		200
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	except: spirit drinks as defined in article 5(1) and sales denominations listed in Annex II, paragraphs 1-14 of Regulation (EC) No 110/2008 and spirits (preceded by the name of the fruit) obtained by maceration and distillation, London Gin, Sambuca, Maraschino, Marrasquino or Maraskino and Mistrà	200
14.2.7.1	Aromatised wines	Except *americano*, *bitter vino*	200
14.2.7.2	Aromatised wine-based drinks	except *bitter soda*, *sangria*, *claria*, *zurra*	200
14.2.7.3	Aromatised wine-product cocktails		200
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol	only alcoholic drinks with less than 15 % of alcohol	200
15.1	Potato-, cereal-, flour- or starch-based snacks	excluding extruded or expanded savoury snack products	100
15.1	Potato-, cereal-, flour- or starch-based snacks	only extruded or expanded savoury snack products	200
15.2	Processed nuts	only savoury-coated nuts	100
16	Desserts excluding products covered in categories 1, 3 and 4		150
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms		300
17.2	Food supplements supplied in a liquid form		100
17.3	Food supplements supplied in a syrup-type or chewable form	only solid food supplements	300
17.3	Food supplements supplied in a syrup-type or chewable form	only liquid food supplements	100

(a): Maximum individually or for the combination of E 100, E 102, E 104, E 110, E 120, E 122, E 124, E 160e and E 161b

(b): Maximum individually or for the combination of E 102, E 104, E 110, E 120, E 122, E 124, E 142, E 151, E 160e and E 161b
(c): Maximum individually or for the combination of E 102, E 110, E 120, E 122, E 124, E 129, E 142, E 151, E 160e and E 161b
(d): Maximum individually or for the combination of E 102, E 110, E 120, E 124, E 151 and E 160e
QS, quantum satis

3.2. Reported use levels or data on analytical levels of β-apo-8'-carotenal (E 160e)

Most food additives in the EU are authorised at a specific MPL. However, a food additive may be used at a lower level than the MPL. For those additives where no MPL is set and which are authorised as quantum satis (QS), information on actual use levels is required.

In December 2006, EFSA issued a public call[6] for scientific data on β-apo-8'-carotenal (E 160e), including present use and use patterns (i.e. which food categories and subcategories, proportion of food within categories/subcategories in which it is used, actual use levels (typical and maximum use levels), especially for those uses which are only limited by quantum satis). In addition, in the framework of Regulation (EC) No 1333/2008 on food additives and of Regulation (EU) No 257/2010 regarding the re-evaluation of approved food additives, in 2013 EFSA issued a new public call[7] for concentration data (usage and/or analytical data) on β-apo-8'-carotenal (E 160e).

In response to the public call for concentration data launched in March 2013, updated information on the actual use levels of β-apo-8'-carotenal (E 160e) in foods was made available to EFSA for some food categories of finished products by FoodDrinkEurope (FDE), the Natural Colours Association (NATCOL), the International Chewing Gum Association (ICGA) and the Association of the European Self-Medication Industry (AESGP). In addition, some analytical data on β-apo-8'-carotenal (E 160e) in soft drinks have been provided from one Member State (Cyprus).

Summarised data on reported use levels in foods from industries and other sources

Appendix A presents data on the levels of β-apo-8'-carotenal (E 160e) in foods as reported by industries in September and October 2013.

Usage levels of β-apo-8'-carotenal (E 160e) in food were provided for the following food categories: confectionery, chewing gum, decorations, coatings and fillings, processed fish, seasonings and condiments, soups and broths, sauces, flavoured drinks and food supplements. Additional data on β-apo-8'-carotenal (E 160e) concentration in a relatively small number of samples in food (*n*=12) and beverages *(n*=7) were provided: for cheese (*n*=1), confectionery (*n*=7), fine bakery wares (*n*=2), desserts (*n*=2) and flavoured drinks (*n*=7). Some information was also provided on the frequency of occurrence of β-apo-8'-carotenal in different foods and beverages in the market (Tennant, 2013).

Analytical data (*n*=47) on β-apo-8'-carotenal (E 160e) in soft drinks (juices, nectars and flavoured drinks) were also provided from a national monitoring programme from one Member State (Cyprus). Some samples (*n*=9) showed the presence of β-apo-8'-carotenal (E 160e) in food categories (14.1.2 – juices and 14.1.3 – nectars) where this food additive is not authorised (Regulation (EC) No 1333/2008). Of the remaining ones, referring to flavoured drinks (food category 14.1.4 - excluding chocolate milk and malt products), the majority (*n*=32) were below the limit of detection (LOD), whereas the few values reported above the LOD (*n*=6) were above the MPL authorised for β-apo-8'-carotenal (E 160e) in this food category (100 mg/l). Data resulting from non-authorised uses or above MPL from authorised uses of β-apo-8'-carotenal (E 160e) were not considered in the exposure assessment.

[6] Call for scientific data on food colours to support re-evaluation of all food colours authorised under the EU legislation. Published: 8 December 2006. http://www.efsa.europa.eu/en/dataclosed/call/afc061208.htm
[7] Call for food additives usage level and/or concentration data in food and beverages intended for human consumption. Published: 27 March 2013. http://www.efsa.europa.eu/en/data/call/130327.htm

3.3. Food consumption

3.3.1. EFSA Comprehensive European Food Consumption Database

In 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) was built from existing national information on food consumption at a detailed level. Competent authorities in the European countries 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, 2011a).

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.

Anticipated exposure to β-apo-8'-carotenal (E 160e) from its use as a food additive has been calculated (mean and 95th percentile of consumers only) using the food consumption data at the individual level (e.g. raw data on food consumption by the individual consumer). High level consumption was only calculated for those foods and population groups where the sample size was sufficiently large to allow calculation of the 95th percentile (EFSA, 2011a). The Panel estimated chronic exposure for the following population groups: toddlers, children, adolescents, adults and the elderly. Calculations were performed using individual body weights.

Thus, for the present assessment, food consumption data were available from 26 different dietary surveys carried out in 17 different European countries (Table 3).

Table 3: Population groups considered for the exposure estimates of β-apo-8'-carotenal (E 160e)

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[8]	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[8]	Older than 65 years	Belgium, Denmark, Finland, France, Germany, Hungary, Italy

Consumption records in the EFSA Comprehensive Database were codified according to the FoodEx classification system (EFSA, 2011b). Nomenclature from the FoodEx classification system was linked to the Food Classification System (FCS) as presented in the Annex II of Regulation (EC) No 1333/2008, part D, to perform exposure estimates.

3.3.2. Food items selected for the refined exposure assessment of β-apo-8'-carotenal (E 160e)

The food categories in which the use of β-apo-8'-carotenal (E 160e) is authorised were selected from the nomenclature of the Comprehensive Database (FoodEx classification system codes), at a detailed level (up to FoodEx level 3) (EFSA, 2011a).

[8] 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).

Some foods in which the use of β-apo-8'-carotenal (E 160e) is authorised are not referenced in the FoodEx classification system and therefore could not be taken into account in the present exposure assessment. These are described below (in ascending order of the Food Classification System codes):

- **1.7.3. Edible cheese rind:** this food category is not referenced in the FoodEx classification system.

- **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.

- **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. fine 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.

- **8.2.3. Casings, coatings and decorations for meat:** this food category is not referenced in the FoodEx classification system and therefore not taken into account.

- **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.

This results in an underestimation of exposure.

Other limitations of the current exposure estimates, which are due to the linkage between the FoodEx classification system and the FCS (Annex II of Regulation (EC) No 1333/2008), are listed below (in ascending order of FCS codes). This results in an overestimation of exposure:

- **5.2. Other confectionery including breath freshening microsweets:** it is not possible within the FoodEx to differentiate candied fruits and vegetables, therefore the MPL of 300 mg/kg was assigned to the entire food group.

- **9.2. Processed fish and fishery products including mollusks and crustaceans:** it is not possible within FoodEx to differentiate fish paste, crustacean paste, surimi, precooked crustacean and smoked fish. Thus, the highest MPL was assigned to the whole food group i.e. 500 mg/kg.

- **15.1. Potato-, cereal-, flour- or starch-based snacks:** the MPL of 200 mg/kg was applied to the whole food group.

- **17. Food supplements**: it is not possible to differentiate the form of the food supplements within FoodEx codes, thus the MPL of 300 mg/kg was applied for the whole food group of food supplements.

For the following food groups, the restrictions as provided in the legislation were not taken into account and food consumption data corresponding to the entire food groups were used to perform the exposure estimate:

- **1.6.3. Other creams:** the restriction 'only flavoured creams' could not be taken into account. The entire food category '1.6 – creams' was considered in the exposure assessment.

- **1.7.1. Unripened cheese, excluding products falling in category 16:** the restriction 'only flavoured unripened cheese' could not be taken into account.

- **1.7.5. Processed cheese:** the restriction 'only flavoured processed cheese' could not be taken into account.

- **12.2.2. Seasonings and condiments:** the entire food category 12.2 'seasonings and condiments' was considered in the exposure assessment.

- **12.6. Sauces:** the entire food category was considered, including tomato-based sauces.

- **12.9. Protein products, excluding products covered in category 1.8:** the restriction 'only meat and fish analogues based on vegetable proteins' was not taken into account in the exposure assessment.

For the following food categories, further refinements were made:

- **14.1.4. Flavoured drinks**: chocolate milk and malt products, as well as cola beverages, which are not likely to contain β-apo-8'-carotenal, were excluded from the exposure estimate.

- **14.2. Alcoholic beverages, including alcohol-free and low-alcohol counterparts:** beers and wines were not taken into account in the exposure estimates, as these are not likely to contain β-apo-8'-carotenal, but restrictions applying to other alcoholic beverages could not be taken into account.

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

3.3.3. Exposure to β-apo-8'-carotenal (E 160e) from its use as a food additive

Dietary exposure to β-apo-8'-carotenal (E 160e) from its use as a food additive was calculated by using (1) MPLs as listed in Table 2, and by using (2) data on reported levels or analytical data as provided by industry and listed in Appendix B, both combined with national consumption data for the five population groups (Table 3).

Two scenarios were taken into account when reported use levels were considered. In the first scenario (UL1), maximum reported levels provided by industries were used. When no actual usage levels for β-apo-8'-carotenal (E 160e) were provided to EFSA for a food category, it was assumed that β-apo-8'-carotenal (E 160e) is not used in this food category. When more than one levels for β-apo-8'-carotenal (E 160e) were reported by industry in a given food category, the highest level provided was used in the exposure assessment.

For the second scenario (UL2), where no reported data had become available to EFSA for a food category, the MPL was used for this food category. For food categories where analytical data were available, these were not taken into account in the exposure calculation; instead, the MPL or usage data, were used.

Table 4 summarises the estimated exposure to β-apo-8'-carotenal (E 160e) from its use as a food additive for all five population groups.

Table 4: Summary of anticipated exposure to β-apo-8'-carotenal (E 160e) from its use as a food additive, by age class (mg/kg bw/day). The minimum and maximum of mean and 95th percentile estimated exposure values across European dietary surveys are shown.

	Toddlers (12-35 months)	Children (3-9 years)	Adolescents (10-17 years)	Adults (18-64 years)	The elderly (> 65 years)
Estimated exposure using MPLs					
• Mean	1.0-3.9	1.0-3.3	0.5-1.7	0.3-1.1	0.2-0.6
• High level[9]	2.8-7.4	2.4-6.7	1.0-3.4	0.8-2.4	0.6-1.5
Estimated exposure using reported use levels or analytical data (UL1)					
• Mean	0.02-0.25	0.02-0.24	0.02-0.14	0.01-0.09	0.01-0.06
• High level[9]	0.06-0.49	0.07-0.46	0.07-0.32	0.04-0.20	0.04-0.14
Estimated exposure using reported use levels (UL2)					
• Mean	0.9-2.5	0.7-2.2	0.2-0.8	0.2-0.5	0.1-0.4
• High level[9]	2.4-6.1	1.4-5.1	0.5-1.8	0.4-1.2	0.4-0.9

3.3.4. Main food categories contributing to exposure to β-apo-8'-carotenal (E 160e) using MPLs

Table 5: Main food categories contributing to exposure to β-apo-8'-carotenal (E 160e) using MPLs (> 5 % to the total mean exposure) and number of surveys in which each food category is contributing.

		Toddlers	Children	Adolescents	Adults	The elderly
FCS category number	**Foods**	**range of % contribution to the total exposure (Number of Surveys) [(a)]**				
1.4	Flavoured fermented milk products including heat-treated products	6-69 (7)	1-35 (13)	1-14 (9)	0-31 (12)	4-28 (6)
7.2	Fine bakery wares	2-51 (6)	4-46 (13)	3-45 (11)	0-42 (14)	0-31 (6)
14.1.4.1	Flavoured drinks with sugar	0-20 (4)	3-43 (14)	5-55 (12)	3-42 (12)	1-38 (3)
3	Edible ices	0-14 (2)	2-12 (10)	2-10 (3)	1-9 (3)	0-6 (2)
16	Desserts excluding products covered in categories 1, 3 and 4	0-13 (2)	0-10 (5)	0-7 (1)	0-5 (2)	0-7 (1)
12.6	Sauces	0-12 (4)	1-23 (12)	2-33 (10)	3-33 (14)	3-27 (6)
1.7.5	Processed cheese	0-11 (2)	-	-	-	-
14.1.4.2	Flavoured drinks with sweeteners	0-8 (1)	0-6 (3)	0-15 (4)	0-24 (5)	0-6 (1)
1.7.1	Unripened cheese (excluding products falling in category 16)	0-7 (4)	0-15 (4)	0-18 (1)	1-24 (6)	2-22 (5)

[9] Typically the 95th percentile of consumers only.

Table 5 : Main food categories contributing to exposure to β-apo-8'-carotenal (E 160e) using MPLs (> 5 % to the total mean exposure) and number of surveys in which each food category is contributing continued.

		Toddlers	Children	Adolescents	Adults	The elderly
FCS category number	**Foods**	**range of % contribution to the total exposure (Number of Surveys) (a)**				
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	-	-	-	1-18 (6)	1-13 (4)
12.5	Soups and broths	0-6 (1)	0-13 (3)	0-12 (1)	0-16 (3)	0-16 (2)
12.2	Herbs, spices, seasonings	0-8 (2)	0-5 (1)	0-11 (1)	0-15 (1)	0-17 (1)
9.2	Processed fish and fishery products including mollusks and crustaceans	0-8 (2)	0-15 (5)	0-7 (4)	0-10 (3)	0-5 (1)
5.2.1	Other confectionery with added sugar	-	0-10 (6)	0-10 (3)	0-9 (2)	0-6 (1)
1.6	Cream	0-6 (1)	0-7 (1)	-	1-13 (4)	1-14 (3)
15.1	Potato-, cereal-, flour- or starch-based snacks	0-7 (2)	1-5 (1)	1-9 (3)	-	-

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

3.3.5. Main food categories contributing to exposure to β-apo-8'-carotenal (E 160e) using reported use levels or reported data on analytical levels

Table 6: Main food categories contributing to exposure to β-apo-8'-carotenal (E 160e) using reported use levels or reported data on analytical levels (> 5 % to the total mean exposure) following scenario 1 (UL1) and number of surveys in which each food category is contributing.

		Toddlers	Children	Adolescents	Adults	The elderly
FCS category number	**Foods**	**range of % contribution to the total exposure (Number of Surveys) [(a)]**				
14.1.4.1	Flavoured drinks with sugar	0-40 (4)	9-55 (15)	8-80 (12)	4-73 (14)	3-73 (5)
12.6	Sauces	1-29 (6)	2-41 (14)	3-43 (11)	10-55 (15)	8-55 (7)
5.2.1	Other confectionery with added sugar	4-36 (6)	5-56 (15)	2-35 (11)	0-39 (10)	0-33 (3)
12.5	Soups and broths	0-28 (4)	0-42 (7)	0-41 (5)	0-51 (7)	0-51 (3)
12.2	Herbs, spices, seasonings	0-26 (3)	0-18 (2)	0-35 (1)	0-44 (4)	0-43 (3)
16	Desserts excluding products covered in categories 1, 3 and 4	0-44 (3)	0-14 (4)	0-11 (1)	0-9 (2)	0-12 (1)
14.1.4.2	Flavoured drinks with sweeteners	0-20 (3)	0-12 (6)	0-18 (4)	0-30 (8)	0-9 (2)
7.2	Fine bakery wares	2-21 (4)	1-27 (8)	1-20 (8)	0-18 (10)	0-14 (4)
9.2	Processed fish and fishery products including mollusks and crustaceans	0-8 (2)	0-20 (2)	0-6 (2)	-	-
5.2.2	Other confectionery without added sugar	-	-	-	-	-
17.	Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children	0-11 (1)	-	-	0-19 (5)	0-49 (2)

(a): The total number of surveys may be greater than the total number of countries listed in Table 2, as some countries submitted more than one survey for a specific age range.

Table 7: Main food categories contributing to exposure to β-apo-8'-carotenal (E 160e) using reported use levels or reported data on analytical levels (> 5 % to the total mean exposure)
following scenario 2 (UL2) and number of surveys in which each food category is contributing.

		Toddlers	Children	Adolescents	Adults	The elderly
FCS category number	**Foods**	**range of % contribution to the total exposure (Number of Surveys) [(a)]**				
1.4	Flavoured fermented milk products including heat-treated products	8-77 (7)	2-46 (13)	2-29 (10)	1-42 (14)	6-35 (7)
7.2	Fine bakery wares	3-66 (6)	5-67 (15)	9-56 (12)	0-55 (14)	0-49 (6)
1.7.1	Unripened cheese (excluding products falling in category 16)	0-10 (6)	0-19 (7)	0-24 (4)	1-31 (9)	4-29 (5)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	-	-	0-5 (1)	2-31 (10)	1-17 (4)
5.2.1	Other confectionery with added sugar	0-5 (1)	1-23 (7)	1-27 (7)	0-21 (5)	0-8 (2)
1.6	Cream	0-6 (1)	0-9 (3)	0-9 (2)	1-25 (4)	1-25 (3)
3	Edible ices	0-20 (3)	3-21 (14)	5-14 (12)	1-12 (10)	0-7 (3)
16	Desserts excluding products covered in categories 1, 3 and 4	0-16 (3)	0-13 (6)	0-11 (3)	0-11 (3)	0-10 (2)
15.1	Potato-, cereal-, flour- or starch-based snacks	0-9 (2)	1-6 (6)	2-16 (7)	1-7 (5)	-
14.1.4.1	Flavoured drinks with sugar	-	0-7 (1)	0-11 (2)	0-7 (2)	0-5 (1)
1.7.5	Processed cheese	0-12 (2)	-	-	-	0-5 (1)
12.5	Soups and broths	-	0-7 (1)	0-7 (1)	0-9 (1)	0-8 (1)
12.6	Sauces	-	0-5 (1)	0-7 (3)	0-6 (5)	-
12.4	Mustard	-	-	-	0-7 (1)	0-5 (1)
17	Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children	-	-	-	-	0-5 (1)

(a): The total number of surveys may be greater than the total number of countries listed in Table 2, as some countries submitted more than one survey for a specific age range.

3.4. Uncertainty analysis

Uncertainties in the exposure assessment of β-apo-8'-carotenal (E 160e) have been previously discussed in the present opinion in the related chapters. In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and are summarised in Table 8:

Table 8: Qualitative evaluation of influence of uncertainties

Sources of uncertainties	Direction[(a)]
Consumption data: different methodologies / representativeness / under reporting / misreporting / no portion size standard	+/-
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 model: uncertainty in possible national differences in use levels of food categories, data set not fully representative of foods on the EU market, exposure calculations based on the maximum reported use levels (no use of typical use levels when available)	+

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

3.5. Discussion

The Panel evaluated a new report (Hard, 2012) reviewing the significance of eosinophilic droplets in the kidneys of both sexes observed at all dose levels of β-apo-8'-carotenal active ingredient/kg bw/day. The material was most prominent in the cortical tubules of female rats exposed to 100 mg/kg bw/day. Hard (2012) suggested that it was very likely that the eosinophilic material represented accumulation of the test compound or a derivative during normal renal processing. The persistence of a reduced amount of the accumulating material in proximal convoluted tubule cells of the kidneys at the end of the four-week recovery period indicated that the material was eliminated, but at a relatively slow rate. However, at the high dose of 100 mg/kg bw/day, a rare condition of cell detachments was suspected, accompanied by very occasional mitotic figures, which suggested that the normal ability of the proximal tubule to repair proximal convoluted tubule cells affected by the accumulated material might have marginally been exceeded at this dose. Based on these observations, the author concluded that 30 mg/kg bw/day represented a NOAEL, since no microscopic evidence of tubule injury was observed at this dose. The Panel agreed with this conclusion.

In its previous opinion (EFSA ANS Panel, 2012) the Panel considered long-term carcinogenicity studies on β-apo-8'-carotenal (Schärer and Studer, 1961). β-Apo-8'-carotenal was administered at approximately 40 mg/kg bw/day to the first generation of Wistar rats and their offspring for a period of two years and no adverse effects were identified, including in the kidney. In addition, the NOAELs identified in other toxicity studies evaluated in that opinion were all above 30mg/kg bw/day (EFSA ANS Panel, 2012).

The Panel concluded that based on the NOAEL of 30 mg/kg bw/day from the 13-week study in rats, in which tubular cell injury was observed at 100 mg/kg bw/day, and using an uncertainty factor of 100, an ADI for β-apo-8'-carotenal of 0.3 mg/kg bw/day was established. The Panel considered an uncertainty factor of 100 as sufficient, not needing an extra adjusting factor due to the pivotal study being a subchronic study (and not a chronic study), given the fact that tubular injury was not observed in the two-year study at 40 mg/kg bw/day, the single dose tested.

The Panel was provided with data on usage levels of β-apo-8'-carotenal (E 160e) by the food industry and with data from the food surveillance system. While the latter were not taken into account for the

estimation of exposure due to the small sample size and the few food categories where data were made available, the Panel did perform calculations on exposure based on usage levels provided by industry in order to refine exposure compared to the previous opinion. However, food industry reported usage levels only for some of the food categories where the additive is authorised. The Panel had no evidence to assume that β-apo-8'-carotenal is indeed used in the reported food categories only but had also no evidence that the additive is used in a broader range of categories. Consequently, two different scenarios of refined exposure estimates were calculated as outlined in the exposure section.

Based on the assumption that indeed β-apo-8'-carotenal (E 160e) is only used in those categories where usage levels were provided, exposure estimates were below the ADI of 0.3 mg/kg bw/day for all population groups at the mean, but exceeded the ADI at high level consumption for toddlers and children and was at the ADI for adolescents. Main contributors in this scenario (UL1) were flavoured drinks (up to 80 %), sauces (up to 55 %), other confectionery (up to 56 %), soups and broths (up to 51 %), and food supplements (up to 49 %).

Exposure scenarios using either the MPLs or the combination of usage levels provided by industry and of MPLs for those food categories were no usage of the colour was reported (UL2) resulted in exceedance of the ADI for all population groups at mean and high level of exposure. For this scenario, the main contributors were flavoured fermented milk products (up to 77 %) and fine bakery wares (up to 67 %).

Refined exposure estimates on tier 3 in the previous opinion were based on the data provided by food industry assuming that β-apo-8'-carotenal is being used in the entire food category while usage levels were in some cases provided for specific food items not representing the entire category. However, only few categories were taken into account for these exposure calculations. New data provided indicated that β-apo-8'-carotenal is being used in a broader range of food categories. This has been taken into account in the new exposure calculation leading to exposure estimates being in a similar range as compared to those from the previous opinion.

Usage levels provided by industry were based on the data reported from member companies and data based on analysis on a relatively small number of samples. According to the data provider, the samples for chemical analysis were selected based on the colour of the product, the primary presence of β-apo-8'-carotenal as the only colour added to foods placed on the European market between 2008 and 2013 and in order to obtain as many products of different types as possible. From these data, the highest reported level was used for the exposure estimates in scenario UL1, although for the category "other confectionery with added sugar" only one product from one supplier contained β-apo-8'-carotenal at the level reported. In addition, the report on usage levels made available to the Panel pointed out, that β-apo-8'-carotenal is a niche colour for very specific applications (e.g. adjusting the shade of orange colour resulting from the use of other colours, mainly beta-carotene). The report also provided some evidence that β-apo-8'-carotenal is only used in 0.8 % of all products in the category "flavoured drinks with sugar" or "flavoured drinks with sweeteners". Taking all this information and the limitations indicated in the exposure section into account, the Panel considers it likely that exposure to β-apo-8'-carotenal is lower than the exposure estimates provided in scenario UL1.

CONCLUSIONS

The Panel concluded that based on the NOAEL of 30 mg/kg bw/day from the 13-week study in rats, in which tubular cell injury was observed at 100 mg/kg bw/day, and using an uncertainty factor of 100, an ADI for β-apo-8'-carotenal of 0.3 mg/kg bw/day was established. The Panel considered an uncertainty factor of 100 as sufficient, not needing an extra adjusting factor due to the pivotal study being a sub-chronic study (and not a chronic study), given the fact that tubular injury was not observed in the 2-year study at 40 mg/kg bw/day, the single dose tested.

Scenarios used for the exposure assessment based on the MPLs or use levels in reported categories combined with the MPLs for other categories led to an exceedance of the ADI up to 10-20 fold in all population groups, both at mean and high level exposure.

However, a further refined exposure scenario was based only on the limited number of categories where industry reported use levels and analytical data. Exposure estimates using this scenario were below the ADI at the mean level for all population groups. At high level of exposure, the ADI was exceeded for toddlers and children, and the exposure for adolescents was at about the ADI. The Panel considered that this high level exposure estimate was still conservative and concluded that these exceedances are unlikely to occur. The Panel concluded that using data provided by the food industry, which are based only on a limited number of regulated categories, the reported uses and use levels of β-apo-8'-carotenal (E 160e) would not be of safety concern.

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ABBREVIATIONS

ADI	acceptable daily intake
ANS	Scientific Panel on Food Additives and Nutrient Sources added to Food
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
LOAEL	lowest observed adverse effect level
MNH	multinucleated hepatocytes
MPL	maximum permitted level
NDNS	UK National Dietary and Nutrition Survey
NOAEL	no observed adverse effect level

APPENDICES

Appendix A. Summary of levels of β-apo-8'-carotenal (E 160e) provided by industry (mg/kg or mg/l)

FCS category No	Food categories	MPL	Restrictions/exceptions	Levels reported		Information provided by
				Typical/ mean	Max	
1.4	Flavoured fermented milk products including heat-treated products	150		–	–	
1.6.3	Other creams	150	only flavoured creams	–	–	
1.7.1	Unripened cheese excluding products falling in category 16	150	only flavoured unripened cheese	–	0.4[(e)]	NATCOL
1.7.3	Edible cheese rind	QS		–	–	
1.7.5	Processed cheese	100[(a)]	only flavoured processed cheese	–	–	
1.7.6	Cheese products (excluding products falling in category 16)	100	only flavoured unripened products	–	–	
3	Edible ices	150		–	–	
4.2.4.1	Fruit and vegetable preparations excluding compote	200	only mostarda di frutta	–	–	
5.2.	Other confectionery including breath freshening microsweets	300	except candied fruit and vegetables	20[(e)]	104[(e)]	NATCOL[(f)]
				2.5[(e)]	2.9[(e)]	
		200	only candied fruit and vegetables	2	2	FDE
5.3.	Chewing gum	300		14	25	ICGA
				12.5	15	NATCOL
5.4.	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	500	only decorations, coatings and sauces, except fillings	1-3	3	FDE
5.4.	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	300	only fillings	11	11	FDE
6.6	Batters	500	only batters for coating	–	–	
7.2.	Fine bakery wares	200		1.8[(e)]	3.5[(e)]	NATCOL
8.2.3	Casings and coatings and decorations for meat	500	only decorations and coatings except edible external coating of *pasturmas*	–	–	
8.2.3	Casings and coatings and decorations for meat	QS	only edible casings	–	–	

Appendix A : Summary of levels of β-apo-8'-carotenal (E 160e) provided by industry (mg/kg or mg/l) continued

FCS category No	Food categories	MPL	Restrictions/exceptions	Levels reported		Information provided by
				Typical/ mean	Max	
9.2.	Processed fish and fishery products including molluscs and crustaceans	100[(b)]	only fish paste and crustacean paste	12.5	15	NATCOL
		500	only surimi and similar products and salmon substitutes			
		250[(c)]	only precooked crustacean			
		100[(d)]	only smoked fish			
9.3	Fish roe	300	except Sturgeons' eggs (Caviar)	–	–	
12.2.2	Seasonings and condiments	500	only seasonings, for example curry powder, tandoori	50	50	FDE[(f)]
12.4	Mustard	300		–	–	
12.5	Soups and broths	50		8.5	14	NATCOL
				5	10	FDE
12.6	Sauces	500	including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces	50	50	FDE[(f)]
12.9	Protein products, excluding products covered in category 1.8	100	only meat and fish analogues based on vegetable proteins	–	–	
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	50		–	–	
13.3	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)	50		–	–	
14.1.4	Flavoured drinks	100	excluding chocolate milk and malt products	1-2	1-7	FDE[(f)]
				3.4[(e)]	9.6[(e)]	NATCOL[(f)]
14.2.3	Cider and perry	200	excluding *cidre bouché*	–	–	
14.2.4	Fruit wine and made wine	200		–	–	

Appendix A : Summary of levels of β-apo-8'-carotenal (E 160e) provided by industry (mg/kg or mg/l) continued

FCS category No	Food categories	MPL	Restrictions/exceptions	Levels reported		Information provided by
				Typical/ mean	Max	
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	200	except: spirit drinks as defined in article 5(1) and sales denominations listed in Annex II, paragraphs 1-14 of Regulation (EC) No 110/2008 and spirits (preceded by the name of the fruit) obtained by maceration and distillation, London Gin, Sambuca, Maraschino, Marrasquino or Maraskino and Mistrà	–	–	
14.2.7.1	Aromatised wines	200	except *americano*, *bitter vino*	–	–	
14.2.7.2	Aromatised wine-based drinks	200	except *bitter soda*, *sangria*, *claria*, *zurra*	–	–	
14.2.7.3	Aromatised wine-product cocktails	200		–	–	
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol	200	only alcoholic drinks with less than 15 % of alcohol	–	–	
15.1	Potato-, cereal-, flour- or starch-based snacks	100	excluding extruded or expanded savoury snack products	–	–	
15.1	Potato-, cereal-, flour- or starch-based snacks	200	only extruded or expanded savoury snack products	–	–	
15.2	Processed nuts	100	only savoury-coated nuts	–	–	
16	Desserts excluding products covered in categories 1, 3 and 4	150		6.9[(e)]	10.8[(e)]	NATCOL
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms	300		8.5-260	16-260	AESGP[(f)]
17.2	Food supplements supplied in a liquid form	100		–	–	
17.3	Food supplements supplied in a syrup-type or chewable form	300	only solid food supplements	–	–	
17.3	Food supplements supplied in a syrup-type or chewable form	100	only liquid food supplements	–	–	

(a): Maximum individually or for the combination of E 100, E 102, E 104, E 110, E 120, E 122, E 124, E 160e and E 161b
(b): Maximum individually or for the combination of E 102, E 104, E 110, E 120, E 122, E 124, E 142, E 151, E 160e and E 161b
(c): Maximum individually or for the combination of E 102, E 110, E 120, E 122, E 124, E 129, E 142, E 151, E 160e and E 161b

(d): Maximum individually or for the combination of E 102, E 110, E 120, E 124, E 151 and E 160e
(e): Measured β-apo-8'-carotenal content of foods and beverages reported by industry
(f): Value was reported at a lower level of detail, but was assigned to the higher food categorization level for the exposure assessment.
QS, quantum satis; – use levels were not reported by industry

Appendix B. Summary of reported levels of β-apo-8'-carotenal (E 160e) used in the exposure assessment (mg/kg or mg/l)

FCS category No	Food categories	Scenarios	
		Scenario 1	Scenario 2
1.4	Flavoured fermented milk products including heat-treated products	0	150
1.6.3	Other creams	0	150
1.7.1	Unripened cheese excluding products falling in category 16	0.4[(a)]	150
1.7.5	Processed cheese	0	100
3	Edible ices	0	150
5.2.	Other confectionery including breath freshening microsweets	104[(a)]	300
5.3.	Chewing gum	25	25
7.2.	Fine bakery wares	3.5[(a)]	200
9.2.	Processed fish and fishery products including molluscs and crustaceans	15	15
9.3	Fish roe	0	300
12.2.2	Seasonings and condiments	50	50
12.4	Mustard	0	300
12.5	Soups and broths	14	14
12.6	Sauces	50	50
12.9	Protein products, excluding products covered in category 1.8	0	100
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	0	50
13.3	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)	0	50
14.1.4	Flavoured drinks	9.6[(a), (b)]	7[(b)]
14.2.3	Cider and perry	0	200[(c)]
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008		
14.2.7.1	Aromatised wines		
14.2.7.2	Aromatised wine-based drinks		
14.2.7.3	Aromatised wine-product cocktails		
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol		
15.1	Potato-, cereal-, flour- or starch-based snacks	0	200
15.2	Processed nuts	0	100

Appendix B : Summary of reported levels of β-apo-8'-carotenal (E 160e) used in the exposure assessment (mg/kg or mg/l) continued.

FCS category No	Food categories	Scenarios	
		Scenario 1	Scenario 2
16	Desserts excluding products covered in categories 1, 3 and 4	10.8[(a)]	150
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms	260	260
17.2	Food supplements supplied in a liquid form		
17.3	Food supplements supplied in a syrup-type or chewable form		
17.3	Food supplements supplied in a syrup-type or chewable form		

(a): Measured β-apo-8'-carotenal content of foods and beverages reported by industry
(b): excluding cola beverages
(c): excluding beers and wines

Appendix C. Summary of total estimated exposure to β-apo-8'-carotenal (E 160e) using MPLs and use levels per age class and survey: mean and high level (mg/kg bw/day)[a]

		MPL		UL1		UL2	
Age class	**Survey**	**Mean**	**High level**	**Mean**	**High level**	**Mean**	**High level**
Toddlers	DIPP	1.0	3.2	0.0	0.1	0.9	3.0
	DONALD_2006_2008	1.3	3.4	0.0	0.2	0.9	2.4
	enKid	1.6	n/a	0.0	n/a	1.6	n/a
	INRAN_SCAI_2005_06	1.2	n/a	0.0	n/a	0.9	n/a
	NUTRICHILD	1.2	2.8	0.1	0.2	0.9	2.4
	Regional_Flanders	3.9	n/a	0.3	n/a	2.2	n/a
	VCP_kids	3.4	7.4	0.2	0.5	2.5	6.1
Children	Danish_Dietary_Survey	1.6	2.9	0.1	0.3	0.7	1.4
	DIPP	1.3	3.0	0.1	0.3	1.0	2.3
	DONALD_2006_2008	1.9	4.2	0.1	0.3	1.1	2.2
	EFSA_TEST	1.5	3.5	0.1	0.3	0.8	2.0
	enKid	1.6	3.9	0.1	0.3	1.1	2.7
	INCA2	1.9	3.5	0.1	0.2	1.3	2.5
	INRAN_SCAI_2005_06	1.0	2.4	0.0	0.1	0.8	1.8
	NFA	3.0	5.9	0.2	0.5	1.5	3.2
	NUT_INK05	1.6	3.3	0.1	0.2	1.0	2.2
	NUTRICHILD	1.5	3.5	0.1	0.2	1.0	2.4
	Regional_Crete	1.1	2.4	0.0	0.2	0.9	2.0
	Regional_Flanders	3.3	6.7	0.2	0.4	1.9	4.5
	SISP04	1.9	4.3	0.1	0.3	1.2	2.6
	STRIP	2.7	4.6	0.2	0.5	1.3	2.4
	VCP_kids	3.1	6.2	0.2	0.4	2.2	5.1
Adolescents	AESAN_FIAB	0.5	1.0	0.0	0.1	0.4	0.9
	Childhealth	0.5	1.3	0.0	0.1	0.2	0.5
	Danish_Dietary_Survey	1.1	2.5	0.1	0.3	0.4	1.0
	Diet_National_2004	1.1	2.5	0.1	0.2	0.5	1.1
	EFSA_TEST	1.0	2.5	0.1	0.2	0.5	1.4
	enKid	1.0	2.3	0.1	0.2	0.6	1.4

	INCA2	0.9	1.9	0.0	0.1	0.6	1.3
	INRAN_SCAI_2005_06	0.6	1.5	0.0	0.1	0.4	1.0
	National_Nutrition_Survey_II	1.0	2.4	0.1	0.2	0.4	1.3
	NFA	1.7	3.4	0.1	0.3	0.8	1.8
	NUT_INK05	0.8	1.9	0.1	0.1	0.5	1.2
	SISP04	1.4	3.3	0.1	0.3	0.8	1.8
Adults	AESAN	0.4	1.1	0.0	0.1	0.3	0.8
	AESAN_FIAB	0.3	0.9	0.0	0.0	0.3	0.7
	Danish_Dietary_Survey	0.5	1.3	0.0	0.1	0.2	0.5
	Diet_National_2004	0.8	2.1	0.1	0.2	0.4	1.0
	DNFCS_2003	1.1	2.4	0.1	0.2	0.5	1.2
	EFSA_TEST	0.6	1.3	0.1	0.1	0.3	0.8
	FINDIET_2007	0.4	1.1	0.0	0.1	0.3	0.9
	INCA2	0.6	1.3	0.0	0.1	0.4	0.9
	INRAN_SCAI_2005_06	0.3	0.8	0.0	0.0	0.3	0.6
	National_Nutrition_Survey_II	0.7	1.8	0.1	0.2	0.4	1.0
	National_Repr_Surv	0.3	0.9	0.0	0.1	0.2	0.4
	NDNS	0.7	1.5	0.0	0.1	0.4	0.8
	NSIFCS	0.5	1.2	0.0	0.1	0.3	0.7
	Riksmaten_1997_98	0.7	1.7	0.1	0.1	0.3	0.7
	SISP04	0.6	1.5	0.0	0.1	0.4	0.9
The elderly	Danish_Dietary_Survey	0.3	0.7	0.0	0.1	0.2	0.5
	Diet_National_2004	0.6	1.5	0.1	0.1	0.3	0.9
	FINDIET_2007	0.2	0.6	0.0	0.0	0.1	0.5
	INCA2	0.4	0.9	0.0	0.0	0.3	0.7
	INRAN_SCAI_2005_06	0.2	0.6	0.0	0.0	0.2	0.5
	National_Nutrition_Survey_II	0.6	1.3	0.0	0.1	0.4	0.9
	National_Repr_Surv	0.3	0.8	0.0	0.0	0.2	0.4

(a): 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 on p. 11, Table 1, of the guidance.