

## STATEMENT OF EFSA

### Refined exposure assessment for amaranth (E 123)<sup>1</sup>

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#### ABSTRACT

Following a self-tasking request, the European Food Safety Authority (EFSA) carried out a refined exposure assessment of amaranth (E 123) taking into account additional information on its use in foods. In 2010, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) adopted a scientific opinion on the re-evaluation of amaranth (E 123) used as a food additive. In that opinion, the Panel concluded that the anticipated dietary exposure of the adult population at the high level (97.5<sup>th</sup> percentile) may exceed the Acceptable Daily Intake (ADI) for amaranth (E 123) of 0.15 mg/kg body weight per day. Following this conclusion, EFSA performed a refined exposure assessment for this food colour. New usage data from industry were submitted to EFSA. Further to this, missing usage data were requested from relevant stakeholders through a targeted call and new information and data were provided. With the use of the EFSA Comprehensive European Food Consumption Database, a refined exposure assessment was performed for amaranth (E 123). Dietary exposure for adults at the 95<sup>th</sup> percentile (up to 55.7 µg/kg bw/day) is about 15 times lower than that in the previous exposure assessment carried out in 2010. Overall, the refined exposure estimates for children, as well as for adults and the elderly, remain below the ADI.

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#### KEY WORDS

amaranth, E 123, dietary exposure, EFSA Comprehensive European Food Consumption Database, food colours

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## SUMMARY

Following the adoption by the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) of a scientific opinion on the re-evaluation of amaranth (E 123) used as a food additive in 2010, in which the Panel concluded that the anticipated dietary exposure of the adult population at the high level may exceed the Acceptable Daily Intake (ADI), EFSA carried out a refined exposure assessment for this food colour, taking also into account additional information on its use and usage levels in foods.

Amaranth (E 123) is a food additive authorised as a food colour in the European Union (EU) for use in few foods according to Annex II of Regulation (EC) No 1333/2008<sup>4</sup> of the European Parliament and of the Council on food additives. This food additive has been previously evaluated by the EU Scientific Committee for Food (SCF, 1976, 1979, 1983) and by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1972, 1975, 1978, 1984).

In 2010, the ANS Panel established an ADI of 0.15 mg/kg body weight (bw)/day for amaranth (E 123). The ANS Panel concluded that, based on the data available, it was possible that the use of amaranth in foods may lead to exposure in excess of the ADI for adults (0.88 mg/kg bw/day at the 97.5<sup>th</sup> percentile). The ANS Panel further noted that the main contributors to adults' anticipated exposure were alcoholic beverages and within this category, aperitif wines and *americano*. The ANS Panel also noted that the anticipated dietary exposure of children to amaranth (E 123) at the high percentiles (95<sup>th</sup>/97.5<sup>th</sup>) was about 30 times lower than the ADI.

The present review provides a refined exposure assessment for amaranth (E 123) based on individual food consumption data which became available within the EFSA Comprehensive European Food Consumption Database and new information on the actual uses of amaranth (E 123) in foods as consumed submitted to EFSA by the food industry in 2012 and 2013.

EFSA concluded that in Europe, based on the actual use levels reported, and for the total population, the mean dietary exposure to amaranth for toddlers (12-35 months old) and children (3-9 years old) is up to 0.06 µg/kg bw/day, and 0.6 µg/kg bw/day, respectively, while exposure estimates at the high levels (95<sup>th</sup> percentile) were around zero. For adolescents (10-17 years old), mean and high level (95<sup>th</sup> percentile) dietary exposures to amaranth are respectively up to 4.0 µg/kg bw/day and 11.5 µg/kg bw/day. Mean dietary exposures to amaranth for adults and the elderly range between 0.2 and 8.8 µg/kg bw/day; high level (95<sup>th</sup> percentile) exposure estimates are up to 57.7 µg/kg bw/day.

Based on the Maximum Permitted Levels (MPLs), the mean anticipated dietary exposure to amaranth (E 123) is up to 0.06 µg/kg bw/day for toddlers, 1.6 µg/kg bw/day for children, and up to 4.0 µg/kg bw/day for adolescents. For adults and the elderly, mean dietary exposures to amaranth are up to 8.9 and 8.0 µg/kg bw/day, respectively. At the high levels (95<sup>th</sup> percentile), the estimated exposures are up to 10, 12.7, 55.7 and 57.7 µg/kg bw/day for children, adolescents, adults and the elderly, respectively.

Therefore, dietary exposure estimates to amaranth (E 123) for all population groups are below the ADI of 0.15 mg/kg bw/day (150 µg/kg bw/day).

For adults and the elderly, the results of the current exposure assessment for amaranth (E 123) are considerably lower compared to the evaluation carried out in 2010, due to more food consumption data being available for adults and a detailed nomenclature of food categories, thus allowing a more detailed selection of foods which can contain amaranth.

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<sup>4</sup> OJ L 354, 31.12.2008, p. 16.

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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<sup>5</sup>, sunset yellow<sup>6</sup>, ponceau 4R<sup>7</sup>). The Member States and stakeholders had informed the European Commission that the figures used in these exposure assessments required possibly some updating.

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

Once the necessary preparatory work to enable the realisation of the foreseen refined exposure assessments e.g. the establishment of a correspondence table between the food classification system (FCS) of the new European legislation (Regulation (EU) No 1129/2011<sup>8</sup>) and of the EFSA Comprehensive Food Consumption Database (FoodEx) had been finalised, in its letter of 26 April 2012, EFSA has requested information on the priorities set by the Commission.

On 23 May 2012, the European Commission sent a letter to EFSA setting the priorities for the refined exposure assessments of twelve food colours (Priority 1: caramel colours (E 150a, E 150c and E 150d); Priority 2: curcumin (E 100), amaranth (E 123), brown HT (E 155); Priority 3: azorubine/carmoisine (E 122), allura red AC (E 129), brilliant black BN (E 151); Priority 4: quinoline yellow (E 104), sunset yellow (E 110), ponceau 4R (E 124)) and indicating that revised data on use and use levels for food colours under priorities 2 and 3 were currently being collected by FoodDrinkEurope and should be provided to EFSA once they were available. Similar revised use data for the caramel colours (E 150a, E 150c and E 150d) have been provided by the Commission to EFSA.

## TERMS OF REFERENCE AS PROVIDED BY EFSA

EFSA is to provide refined exposure assessments for food colours already re-evaluated taking into account the restrictions/exceptions listed in Regulation (EU) No 1129/2011, especially in the case of main contributors.

Furthermore, it is requested that following the establishment of a correspondence table between the food classification system of Regulation (EU) No 1129/2011 and of the EFSA Comprehensive Food Consumption Database (FoodEx), EFSA will use the FoodEx system in order to provide refined exposure assessments and exclude non relevant food subgroups from the intake calculations. The list of priorities, as provided by the European Commission, is set as follows:

Priority 1 - caramel colours (E 150a, E 150c, E 150d)

Priority 2 - curcumin (E 100), amaranth (E 123), brown HT (E 155)

Priority 3 - azorubine/carmoisine (E 122), allura red AC (E 129), brilliant black BN (E 151)

Priority 4 - quinoline yellow (E 104), sunset yellow (E 110), ponceau 4R (E 124)

<sup>5</sup> EFSA, 2009. Scientific Opinion on the re-evaluation of Quinoline Yellow (E 104) as a food additive, ON-1329.

<sup>6</sup> EFSA, 2009. Scientific Opinion on the re-evaluation of Sunset Yellow FCF (E 110) as a food additive, ON-1330.

<sup>7</sup> EFSA, 2009. Scientific Opinion on the re-evaluation of Ponceau 4R (E 124) as a food additive, ON-1328.

<sup>8</sup> OJ L 295, 12.11.2011, p.1.

## ASSESSMENT

### 1. Introduction

Amaranth (E 123) is a mono-azo dye authorised as a food additive in the EU. This food colour has been previously evaluated by the Scientific Committee for Food (SCF) in 1976, 1979 and 1983 and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1972, 1975, 1978 and 1984. Amaranth (E 123) has also been reviewed by TemaNord in 2002.

In 2010, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) has re-evaluated amaranth (E 123) as a food additive (EFSA, 2010). The safety of use of amaranth (E 123) was assessed on the basis of uses and use levels authorised in the legislation<sup>9</sup> and of reported use levels, as provided by industry. The ANS Panel established for amaranth an Acceptable Daily Intake (ADI) of 0.15 mg/kg body weight (bw)/day based on the results of a 2-year long-term toxicity study and reproductive and developmental toxicity studies.

The ANS Panel concluded that at the Maximum Permitted Level (MPL) of use and/or reported use levels of amaranth (E 123), estimates of the exposure for children (between 1 to 14 years old) at the high percentiles (95<sup>th</sup>/97.5<sup>th</sup> percentiles) are around 30 times lower than the ADI (ranging from 0 to 0.04 mg/kg bw/day). However, for adults, the anticipated exposure to amaranth at the high percentile (97.5<sup>th</sup>) can be up to 6 times higher than the ADI (0.88 mg/kg bw/day).

The main contributors to the total anticipated exposure of adult population to amaranth (E 123) were aperitif wines and *americano*. The Panel noted that estimates of the exposure to amaranth (E 123) from these uses have been made based on the maximum reported levels of use for aperitif wines, which were reported by industry to be at the same level as the MPLs.

The aim of the present assessment is to provide a refined exposure assessment for amaranth (E 123) from its use as a food colour, using the EFSA Comprehensive European Food Consumption Database and the FoodEx classification system and taking into consideration, besides the MPLs, updated use levels reported by the industry. Some information was received in October 2012. Further to this, and considering that data were missing, especially for the food category 'fish roe', a request for concentration data concerning the usage of amaranth (E 123) in this food category was made by targeting relevant industries. New data were received in February and March 2013.

### 2. Use and use levels of amaranth (E 123)

The use of amaranth (E 123) as a food additive is currently permitted in few food categories: in fish roe and in some alcoholic beverages (e.g. spirit drinks, *americano*, *bitter vino*, aperitif wines, *bitter soda* and alcoholic drinks with less than 15 % of alcohol).

#### 2.1. Maximum Permitted Levels of use

Maximum Permitted Levels (MPLs) of use for amaranth (E 123) have been defined in Annex II of Regulation (EC) No 1333/2008<sup>10</sup> on food additives for use in foods (Table 1).

<sup>9</sup> European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs. OJ L 237, 10.9.1994, p. 13.

<sup>10</sup> Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 354, 31.12.2008, p. 16.

**Table 1:** Food categories in which amaranth (E 123) is authorised to be used as a food additive according to Annex II of Regulation (EC) No 1333/2008

FCS Category No	Food categories	Maximum permitted level (mg/l or mg/kg as appropriate)	Restrictions/exception
9.3	Fish roe	30	except Sturgeons' eggs (Caviar)
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	30	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	100 <sup>(a), (b)</sup>	only <i>americano</i> , <i>bitter vino</i>
14.2.7.1	Aromatised wines	30	only aperitif wines
14.2.7.2	Aromatised wine-based drinks	100 <sup>(c)</sup>	only <i>bitter soda</i>
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol	30	only alcoholic drinks with less than 15 % of alcohol

(a): In *americano* E 100, E 101, E 102, E 104, E 120, E 122, E 123, E 124 are authorised individually or in combination.

(b): In *bitter vino* E 100, E 101, E 102, E 104, E 110, E 120, E 122, E 123, E 124, E 129 are authorised individually or in combination.

(c): In *bitter soda* E 100, E 101, E 102, E 104, E 110, E 120, E 122, E 123, E 124, E 129 are authorised individually or in combination.

## 2.2. Reported use levels of amaranth (E 123)

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.

Updated information on the actual use levels of amaranth (E 123) in foods was provided to EFSA by FoodDrinkEurope for aperitif wines and spirit drinks, including products with less than 15 % alcohol by volume (Category No 14.2.6, 14.2.7.1 and 14.2.8), in October 2012. New data were provided to EFSA by the European Committee of Wine Enterprises (Comité Européen des Entreprises Vins - CEEV) for alcoholic beverages (Categories No 14.2.7.1 and 14.2.7.2), while the European Federation of the Trade in Dried Fruit, Edible Nuts, Processed Fruit and Vegetables, Processed Fishery Products, Spices, Honey and Similar Foodstuffs (FRUCOM) and the Association of Processed Foods Manufacturers (Association Des Entreprises de Produits Alimentaires Elaborés - ADEPALE) provided information on fish roe (Category No 9.3).

No analytical data from any sources (Member States, scientific literature) were collected.

Appendix A shows the use levels provided by industry and used for the refined exposure assessment.

### *Summarised data on reported use levels of amaranth in foods from industries*

The information provided to EFSA covers the two food categories, alcoholic beverages and fish roe, in which amaranth (E 123) is authorised to be used as a food additive.

The maximum use levels reported by industry for alcoholic beverages are equal or almost equal to the MPLs as set in the legislation (Appendix A). Data collected on aperitif wines, were consistent between the two data providers (FoodDrinkEurope, CEEV).

According to the feedback received from the stakeholders (ADEPALE, FRUCOM), amaranth is no longer used in fish roe. Therefore, based on the information provided by the stakeholders, the usage level in the refined exposure estimates for this food category was set to zero.

### **3. Food consumption**

#### **3.1. EFSA 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 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. Nevertheless, the EFSA Comprehensive Database represents the best available source of food consumption data across Europe at present.

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

#### **3.2. Food items selected for the refined exposure assessment of amaranth (E 123)**

The food categories in which the use of amaranth (E 123) 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, 2011b).

The restriction within the food category 9.3 – “Fish roe, except Sturgeons' eggs (Caviar)” could not be taken into account in the present exposure assessment, since no distinction is made in the FoodEx nomenclature between sturgeons' eggs and other fish eggs. Therefore, the whole food category was taken into account; this results in a minor overestimation.

Food codes for alcoholic beverages were chosen at the most detailed level within FoodEx nomenclature, looking also at the level of the original food name in order to identify all food items in which amaranth is authorised. The food categories in which amaranth (E 123) is permitted to be used, as defined in the FoodEx classification system, are broader in comparison to the restrictions set in the legislation e.g. FoodEx classification does not allow for differentiation of *americano* and *bitter vino* from other aromatised wines.

Appendix B shows the food items selected from the EFSA Comprehensive database and used for the refined exposure assessment.

### **4. Dietary exposure assessment**

Dietary exposure to amaranth (E 123) from its use as a food colour was estimated based on the consumption data available within the Comprehensive Database as presented in Section 3, 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, 2011a).

Chronic exposure to amaranth (E 123) 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 2.

**Table 2:** Population groups considered for the exposure estimates of amaranth (E 123)

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 <sup>11</sup>	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 <sup>11</sup>	Older than 65 years	Belgium, Denmark, Finland, France, Germany, Hungary, Italy

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

In summary, FoodEx food codes were matched to the FCS food categories reported in Table 1 (Appendix B). Subsequently, each individual exposure was calculated by using the corresponding individual body weight and based on the assumption that amaranth (E 123) is present in the food at the levels shown in Appendix B. The average and high percentile exposures were calculated for the five population groups described in Table 2.

#### 4.1. Exposure to amaranth (E 123) from its use as a food additive

Table 3 summarises the anticipated refined exposure to amaranth (E 123) from its use as a food additive for the total population for all five population groups (Table 2).

**Table 3:** Summary of anticipated exposure to amaranth (E 123) by age class ( $\mu\text{g}/\text{kg}$  bw/day). The minimum and maximum of mean and 95<sup>th</sup> 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)
<b>Estimated exposure using MPLs</b>					
• Mean	0 <sup>(a)</sup> - 0.06	0 <sup>(a)</sup> - 1.6	0 <sup>(a)</sup> - 4.0	0.4 - 8.9	0.2 - 8.0
• High level (95 <sup>th</sup> percentile)	0 <sup>(b)</sup>	0 <sup>(b)</sup> - 10.0	0 <sup>(b)</sup> - 12.7	0 <sup>(b)</sup> - 55.7	0 <sup>(b)</sup> - 57.7
<b>Estimated exposure using reported use levels</b>					
• Mean	0 <sup>(a)</sup> - 0.06	0 <sup>(a)</sup> - 0.6	0 <sup>(a)</sup> - 4.0	0.4 - 8.8	0.2 - 8.0
• High level (95 <sup>th</sup> percentile)	0 <sup>(b)</sup>	0 <sup>(b)</sup>	0 <sup>(b)</sup> - 11.5	0 <sup>(b)</sup> - 55.7	0 <sup>(b)</sup> - 57.7

(a): Real zero, meaning that none of the foods in which amaranth (E 123) is authorised was reported to be consumed in some surveys.

<sup>11</sup> 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).



(b): Less than 5 % of the population reported consumption of the foods in which amaranth (E 123) is authorised, resulting in an exposure level of 0 at the 95<sup>th</sup> percentile in some surveys.

The total anticipated exposure is very low, compared with the ADI, for all population groups and especially for toddlers. Detailed results by age class and survey are presented in Appendix C.

Considering the low number of food groups in which amaranth (E 123) is permitted to be used, the mean anticipated exposure was also estimated for consumers only (Table 4). The number of surveys in which the consumption level is not zero is indicated in brackets.

**Table 4:** Summary of mean exposure to amaranth (E 123) for consumers only by age class ( $\mu\text{g}/\text{kg}$  bw/day). The minimum and maximum of mean estimated exposure values across European dietary surveys is shown.

	Toddlers (12-35 months)	Children (3-9 years)	Adolescents (10-17 years)	Adults (18-64 years)	The elderly (> 65 years)
<b>Estimated exposure using MPLs</b>					
• Mean	1.8 - 8.1 (2)	0.2 - 107.1 (10)	1.2 - 76.7 (11)	6.6 - 66.2 (15)	6.9 - 50.6 (7)
<b>Estimated exposure using reported use levels</b>					
• Mean	1.8 - 8.1 (2)	0.2 - 107.1 (6)	0.9 - 76.6 (9)	7.5 - 67.5 (15)	6.9 - 50.6 (7)

#### 4.2. Main food categories contributing to exposure to amaranth (E 123)

The main food categories contributing to mean exposure to amaranth (E 123) (> 5 % of total exposure) using MPLs, and the number of surveys in which each food category is a main contributor are shown in Table 5.

**Table 5:** Main food categories contributing to mean exposure to amaranth (E 123) (> 5 % of total exposure) using MPLs, and number of surveys in which each food category is a main contributor. The minimum and maximum values across European dietary surveys are shown.

FCS Category No	Food categories	% contribution to total exposure (Number of Surveys) <sup>(a)</sup>				
		Toddlers	Children	Adolescents	Adults	The elderly
9.3	Fish roe	-	44 - 100 (5)	29 - 100 (4)	10 - 16 (3)	5 (1)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	100 (2)	56 - 100 (6)	53 - 100 (9)	84 - 100 (15)	95 - 100 (7)

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

Toddlers are reported not to consume any fish roe, therefore the category of alcoholic beverages accounts for the entire dietary exposure (100 %) to amaranth (E 123) estimated for this population group. Since consumption of alcoholic beverages is not appropriate for this age group, it should be noted that these exposure estimates, which are very low, are most likely result of indirect consumption of alcoholic beverages (ranging from 0.001 up to 0.02 g/kg bw/day) by toddlers e.g. as recipe ingredient of composite foods.

Since no use levels have been reported for fish roe, as information was provided that amaranth (E 123) is no longer used in this food category, the anticipated mean exposure to amaranth is based on the contribution from alcoholic beverages only when using maximum reported use levels. Therefore, when reported use levels are considered, alcoholic beverages contribute 100 % of the mean exposure to amaranth (E 123), for the same number of surveys as shown in Table 5.

## 5. Results and discussion

EFSA has performed a refined exposure assessment for amaranth (E 123) taking into consideration newly submitted information on its actual uses in fish roe and alcoholic beverages.

The present exposure estimates have been performed using MPLs or the maximum reported use levels provided by industry and based on individual food consumption data available in the EFSA Comprehensive European Food Consumption Database.

The results of the present exposure assessment for amaranth (E 123) are considerably lower than those from the previous exposure assessment performed by the ANS Panel in 2010 (EFSA, 2010), which were based on fewer consumption surveys and previous occurrence data; reported use levels for alcoholic beverages remain the same. In the case of fish roe, reported use levels equal to the MPL were previously used, whereas in the present assessment, reported use levels were assumed to be zero based on feedback from stakeholders.

Toddlers' mean exposure to amaranth (E 123) is nearly zero both for the exposure estimates based on MPLs and for exposure estimates using maximum reported use levels; only for two countries the mean exposure is above zero (up to 0.06 µg/kg bw/day). High level exposures are equal to zero as calculated with both MPLs and maximum reported use levels. Mean anticipated exposures estimated for consumers only range from 1.8 to 8.1 µg/kg bw/day.

Children's mean exposure to amaranth (E 123) estimated with MPLs is above zero for ten countries and at the maximum reaches 1.6 µg/kg bw/day in one country. Mean exposures estimated with maximum reported use levels are above zero in six countries and at the maximum reach 0.6 µg/kg bw/day in one country. Only in two countries, exposure estimates using MPLs are above zero at the high level (95<sup>th</sup> percentile). Mean anticipated exposures estimated for consumers only range from 0.2 to 107.1 µg/kg bw/day.

For the adolescents, mean exposure estimates reach at the maximum 4 µg/kg bw/day in eleven and nine countries, using MPLs or maximum reported use levels, respectively. At the high level (95<sup>th</sup> percentile), exposure estimates reach 12.7 µg/kg bw/day using MPLs and 11.5 µg/kg bw/day using maximum reported use levels. Mean anticipated exposures estimated for consumers only range from 0.9 to 76.7 µg/kg bw/day using MPLs or maximum reported use levels.

For adults, the mean estimated exposures (using either MPLs or maximum reported use levels) range between 0.4 and 8.9 µg/kg bw/day. At the high level (95<sup>th</sup> percentile), using maximum reported use levels, exposure estimates reach up to 55.7 µg/kg bw/day in ten countries. Mean anticipated exposure estimated for consumers only range between 6.6 and 66.2 µg/kg bw/day and between 7.5 and 67.5 µg/kg bw/day using MPLs and maximum reported use levels, respectively.

For the elderly, the mean estimated exposures (using either MPLs or maximum reported use levels) range between 0.2 and 8.0 µg/kg bw/day. At the high levels (95<sup>th</sup> percentile), exposure estimates using the maximum reported use levels reach up to 57.7 µg/kg bw/day in five countries. Mean anticipated exposures estimated for consumers only range between 6.9 and 50.6 µg/kg bw/day using both MPLs and maximum reported use levels.

For all populations, the main contributing food category to the exposure to amaranth (> 5%) is alcoholic beverages. Fish roe is contributing mostly for children and adolescents when estimating dietary exposure based on the MPLs authorised in the legislation.

The current total anticipated dietary exposure to amaranth (E 123) is far below the ADI of 0.15 mg/kg bw/day for all population groups, both at mean and high exposure levels (95<sup>th</sup> percentile). In the previous opinion of the ANS Panel (EFSA, 2010), the estimated total mean and high (95<sup>th</sup>/97.5<sup>th</sup> percentile) dietary exposures to amaranth (E 123) for children were below the ADI; however, for adults, anticipated exposure at the high level (97.5<sup>th</sup> percentile) could be up to 6 times higher than the ADI.

These differences in the outcomes of the current and previous exposure estimates for amaranth (E 123) are mainly due to the new consumption data used and to the refinement in the selection of food items within the FoodEx nomenclature. Indeed, some of the children's consumption surveys currently included in the EFSA Comprehensive Database, were also used in the opinion of the ANS Panel on amaranth in 2010 (EFSA, 2010), but no detailed data (i.e. following the FoodEx nomenclature) were available to EFSA at that time and UK consumption data for adults were retrieved from various reports (Tennant, 2006; Tennant, 2007). Moreover, in this assessment individual food consumption data are used to estimate the dietary exposure, whereas in the 2010 ANS opinion, only summary statistics were used. The updated information regarding the non-usage of amaranth in fish roe, provided by industry, also lowered the exposure estimates for toddlers, children and adolescents.

## 6. Uncertainty analysis

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

**Table 6:** Qualitative evaluation of influence of uncertainties

Sources of uncertainties	Direction <sup>(a)</sup>
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	+
Exposure model: uncertainty in possible national differences in use levels of food categories, dataset not fully representative of foods on the EU market	+/-

(a): + = uncertainty with potential to cause overestimation of exposure; - = uncertainty with potential to cause underestimation of exposure

EFSA considered the impact of the uncertainties in the exposure assessment for amaranth (E 123) and concluded that overall uncertainty could lead to an overestimation of the calculated exposure estimates.

## CONCLUSIONS

The current exposure estimates for amaranth (E 123) provide an update of the exposure estimated in 2010 (EFSA, 2010). For adults and the elderly, exposure estimates differ from those of the previous opinion of the ANS Panel in 2010 (EFSA, 2010). The current exposure estimates (up to 57.7 µg/kg bw/day) are 15 times lower than the 2010 estimates at the high level (95<sup>th</sup> percentile). For children, mean estimated exposures (up to 4 µg/kg bw/day) are almost equal to those of the 2010 assessment, while high exposure (95<sup>th</sup> percentile) estimates are 4 times lower (up to 11.5 µg/kg bw/day).

The differences in the outcome of the exposure estimates are mainly driven by the use of new food consumption data and a refined selection of food items within the FoodEx nomenclature. The updated information regarding the non-usage of amaranth in fish roe, provided by industry, also lowered the exposure estimates for toddlers, children and adolescents.

EFSA concluded that the mean anticipated dietary exposure to amaranth (E 123) using the maximum reported use levels for toddlers and children is up to 0.6 µg/kg bw/day, while at the high levels (95<sup>th</sup> percentile), exposure estimates are equal to zero due to the low number of consumers (below 5 %). For adolescents, the mean anticipated exposure is up to 4 µg/kg bw/day and up to 11.5 µg/kg bw/day at the high level (95<sup>th</sup> percentile), using maximum reported use levels. Anticipated exposure estimates for adults and the elderly range from 0.2 to 8.8 µg/kg bw/day at the mean and up to 57.7 µg/kg bw/day at the high level (95<sup>th</sup> percentile) using maximum reported use levels.

In conclusion, mean exposure estimates, as well as high level (95<sup>th</sup> percentile) exposure estimates for amaranth (E 123) are below the ADI for all populations groups.

#### DOCUMENTATION PROVIDED TO EFSA

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APPENDICES

Appendix A. Summary of use levels of amaranth (E 123) as reported

FCS Category No	Food categories	Maximum Permitted Level (mg/l or mg/kg as appropriate)	Restrictions/exception	Reported use levels (mg/l or mg/kg)				
				FDE		CEEV	ADEPALE	FRUCOM
				Typical level	Maximum level	Typical level		
9.3	Fish roe	30	except Sturgeons' eggs (Caviar)				not used	no longer used
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	30	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	0-20	25-28			
14.2.7.1	Aromatised wines	100 <sup>(a), (b)</sup>	only <i>americano</i> , <i>bitter vino</i>			100		
14.2.7.1	Aromatised wines	30	only aperitif wines	0-20	25-28	30		
14.2.7.2	Aromatised wine-based drinks	100 <sup>(c)</sup>	only <i>bitter soda</i>			100		
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol	30	only alcoholic drinks with less than 15 % of alcohol	0-20	25-28			

(a): In *americano* E 100, E 101, E 102, E 104, E 120, E 122, E 123, E 124 are authorised individually or in combination

(b): In *bitter vino* E 100, E 101, E 102, E 104, E 110, E 120, E 122, E 123, E 124, E 129 are authorised individually or in combination

(c): In *bitter soda* E 100, E 101, E 102, E 104, E 110, E 120, E 122, E 123, E 124, E 129 are authorised individually or in combination

**Appendix B. Food items selected from the EFSA Comprehensive database for the refined exposure assessment of amaranth (E 123)**

<b>FCS Category No</b>	<b>Food categories</b>	<b>FoodEx Category No</b>	<b>FoodEx name</b>	<b>Maximum Permitted Level (mg/l or mg/kg as appropriate)</b>	<b>Reported use levels (mg/l or mg/kg as appropriate)</b>
9.3	Fish roe	A.07.03.001	Fish roe	30	0
14.2.6	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	A.14.05.005	Egg liqueur	30	28
14.2.6	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	A.14.06	Spirits	30	28
14.2.6	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	A.14.06.003	Gin	30	28
14.2.6	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	A.14.06.004	Vodka and vodka-like spirits	30	28
14.2.6	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	A.14.06.006	Spirits made from fruits	30	28
14.2.6	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	A.14.06.007	Spirits made from vegetables (Tequila)	30	28
14.2.7	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	A.14.03	Fortified and liqueur wines	100	100
14.2.7	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	A.14.03.001	Vermouth	30	30
14.2.7	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	A.14.05.001	Fruit liqueur	100	100
14.2.7	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	A.14.05.002	Herb liqueur	100	100
14.2.8	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	A.14.07	Beverages with less than 15 % alcohol	30	28

**Appendix C. Summary of total estimated exposure (using MPLs and reported use levels) per age class and survey: mean and high level ( $\mu\text{g}/\text{kg bw}/\text{day}$ )**

	Number of subjects	MPL		Reported Use levels	
		Mean	High level (95 <sup>th</sup> percentile)	Mean	High level (95 <sup>th</sup> percentile)
<b>Toddlers</b>					
Belgium (Regional_Flanders)	36	0.000		0.000	
Bulgaria (NUTRICHILD)	428	0.042	0.000	0.042	0.000
Germany (DONALD_2006_2008)	261	0.062	0.000	0.062	0.000
Spain (enKid)	17	0.000		0.000	
Finland (DIPP)	497	0.000	0.000	0.000	0.000
Italy (INRAN_SCAI_2005_06)	36	0.000		0.000	
Netherlands (VCP_kids)	322	0.000	0.000	0.000	0.000
<b>Children</b>					
Belgium (Regional_Flanders)	625	0.000	0.000	0.000	0.000
Bulgaria (NUTRICHILD)	433	0.019	0.000	0.019	0.000
Czech Republic (SISP04)	389	0.042	0.000	0.042	0.000
Germany (DONALD_2006_2008)	660	0.014	0.000	0.008	0.000
Denmark (Danish_Dietary_Survey)	490	1.573	10.000	0.000	0.000
Spain (enKid)	156	0.000	0.000	0.000	0.000
Spain (NUT_INK05)	399	0.000	0.000	0.000	0.000
Finland (DIPP)	933	0.013	0.000	0.013	0.000
Finland (STRIP)	250	0.003	0.000	0.000	0.000
France (INCA2)	482	0.135	0.000	0.000	0.000
Greece (Regional_Crete)	839	0.000	0.000	0.000	0.000
Italy (INRAN_SCAI_2005_06)	193	0.003	0.000	0.003	0.000
Latvia (EFSA_TEST)	189	0.567	0.000	0.567	0.000
Netherlands (VCP_kids)	957	0.000	0.000	0.000	0.000
Sweden (NFA)	1473	0.909	6.000	0.000	0.000
<b>Adolescents</b>					
Belgium (Diet_National_2004)	584	3.989	12.712	3.955	11.480
Cyprus (Childhealth)	303	0.114	0.000	0.000	0.000
Czech Republic (SISP04)	298	0.096	0.000	0.096	0.000
Germany (National_Nutrition_Survey_II)	1011	2.503	0.000	2.500	0.000
Denmark (Danish_Dietary_Survey)	479	1.043	7.872	0.558	5.357
Spain (AESAN_FIAB)	86	0.436	0.000	0.436	0.000
Spain (enKid)	209	0.000	0.000	0.000	0.000
Spain (NUT_INK05)	651	2.093	0.000	2.093	0.000
France (INCA2)	973	0.904	0.000	0.885	0.000
Italy (INRAN_SCAI_2005_06)	247	0.042	0.000	0.030	0.000
Latvia (EFSA_TEST)	470	0.377	0.000	0.377	0.000
Sweden (NFA)	1018	0.252	1.250	0.000	0.000



**Appendix C. Summary of total estimated exposure (using MPLs and reported use levels) per age class and survey: mean and high level ( $\mu\text{g}/\text{kg bw}/\text{day}$ ) (continued)**

	Number of subjects	MPL		Use levels	
		Mean	High level (95 <sup>th</sup> percentile)	Mean	High level (95 <sup>th</sup> percentile)
<b>Adults</b>					
Belgium (Diet_National_2004)	1304	8.882	55.743	8.848	55.743
Czech Republic (SISP04)	1666	2.321	8.382	2.321	8.382
Germany (National_Nutrition_Survey_II)	10419	1.779	3.529	1.776	3.409
Denmark (Danish_Dietary_Survey)	2822	2.840	13.092	2.547	12.667
Spain (AESAN)	410	0.614	0.000	0.513	0.000
Spain (AESAN_FIAB)	981	0.756	0.000	0.738	0.000
Finland (FINDIET_2007)	1575	2.571	5.473	2.520	2.683
France (INCA2)	2276	5.864	33.092	5.827	33.092
United Kingdom (NDNS)	1724	7.124	38.267	7.108	38.267
Hungary (National_Repr_Surv)	1074	0.546	0.000	0.546	0.000
Ireland (NSIFCS)	958	4.294	19.352	4.293	19.352
Italy (INRAN_SCAI_2005_06)	2313	0.440	0.045	0.435	0.000
Latvia (EFSA_TEST)	1306	1.123	0.000	1.115	0.000
Netherlands (DNFCS_2003)	750	3.969	11.000	3.969	11.000
Sweden (Riksmaten_1997_98)	1210	4.172	16.749	3.538	16.327
<b>The elderly</b>					
Belgium (Diet_National_2004)	1230	7.974	57.692	7.953	57.692
Germany (National_Nutrition_Survey_II)	2496	0.971	1.071	0.969	0.536
Denmark (Danish_Dietary_Survey)	329	4.975	18.219	4.709	17.857
Finland (FINDIET_2007)	463	2.630	6.129	2.564	3.022
France (INCA2)	348	3.744	16.611	3.709	16.611
Hungary (National_Repr_Surv)	286	0.373	0.000	0.373	0.000
Italy (INRAN_SCAI_2005_06)	518	0.174	0.000	0.174	0.000

**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
FCS	Food Categorisation System (food nomenclature) presented in the Commission Regulation (EU) N° 1129/2011
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MPL	Maximum Permitted Level
SCF	Scientific Committee for Food