STATEMENT OF EFSA

Revised exposure assessment for lycopene as a food colour[1]

European Food Safety Authority[2, 3]

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ABSTRACT

Following a request from the Commission, a revised exposure assessment of lycopene from use as a food colour and from natural occurrence, for children and adults, was carried out using the proposed revised maximum and typical use levels according to a range of scenarios defined in the terms of reference, and with reference to the exposure assessment presented in the former opinion on lycopene by the EFSA's Panel on Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC). Several food consumption databases were used to conduct the current exposure assessment. For children, data of the EXPOCHI project, UK data and additional French data were used. Estimates for adults were based on UK data only. Overall, the revised exposure assessment of lycopene from both the use as a food colour and the natural occurrence indicated that the potential average exposures for children were approximately of 200 µg/kg bw/day, and around or slightly below the ADI at the 95th percentile. In adults, the high exposure (95th percentile) to lycopene from use as a food colour and from natural origin was below the ADI. When exposure to lycopene from fortified foods was also included, the conservative estimates of the exposure were much higher in all populations studied. EFSA concluded that in this case, potential intakes might exceed the ADI, particularly for children. About 50 to 65% of the total exposure to lycopene (excluding lycopene added as a novel food ingredient) was originating from natural sources. The current revised exposure estimates indicated that, based on typical use levels, desserts, including flavoured milk products, non-alcoholic beverages and fine bakery products are important sources of lycopene from food colours.

KEY WORDS

Lycopene, natural occurrence, food colour, novel food ingredient, exposure

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SUMMARY

Following a request from the Commission, a revised exposure assessment of lycopene from use as a food colour and from natural occurrence, for children and adults, was carried out using the proposed revised maximum and typical use levels according to a range of scenarios defined in the terms of reference, and with reference to the exposure assessment presented in the former opinion by the EFSA's Panel on Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC). EFSA noted that most of the use levels were reduced considerably compared to those considered in former EFSA evaluations.

Several food consumption databases were used to conduct the current exposure assessment. For children, data from the EXPOCHI project, UK data and additional French data were used. Estimates for adults were based on UK data only.

The data from the EXPOCHI project could only be used to calculate the exposure to added lycopene from its uses as a food colour and as a novel food ingredient. For children, additional estimates from French and available UK data were used to assess the exposure to lycopene from natural occurrence, and the total exposure to lycopene (from added sources - uses as a food colour and/or novel food ingredient - and from natural occurrence).

In French and UK children, the intake of lycopene from natural sources (naturally-occurring lycopene - scenario 1) was 131 and 140 µg/kg bw/day at the mean and 322 and 440 µg/kg bw/day at the 95th percentile, respectively. In French children, anticipated exposure estimates based on typical use levels of lycopene as a food additive and also including naturally-occurring lycopene, were approximately 200 µg/kg bw/day (mean) and 411-417 µg/kg bw/day (95th percentile) without fortified foods (scenario 2 to 4), and approximately 423 µg/kg bw/day (mean) and 775 µg/kg bw/day (95th percentile) when potential fortified foods were included (scenarios 5 and 6). In UK children, the anticipated exposure ranged from 180 µg/kg bw/day (mean) and 480 µg/kg bw/day (95th percentile) (scenario 2), to 210 µg/kg bw/day (mean) and 520 µg/kg bw/day (95th percentile) (scenario 4), whereas the potential exposure increased to approximately 500 µg/kg bw/day (mean) and nearly 770 µg/kg bw/day (95th percentile) after adding the exposure arising from fortified foods.

In adults, intake of lycopene from natural occurrence (scenario 1) was 84 µg/kg bw/day (mean) and 300 µg/kg bw/day (95th percentile). In scenarios 2 to 4, mean exposure to lycopene ranged from 102 to 139 µg/kg bw/day, and high level exposures (285-322 µg/kg bw/day) were below the Acceptable Daily Intake (ADI). When exposure to lycopene from fortified foods was also included (scenarios 5 and 6), the exposure amounted to 201 and 222 µg/kg bw/day (mean) and 353 and 375 µg/kg bw/day (95th percentile), respectively.

About 50 to 65% of the total exposure to lycopene (excluding lycopene added as a novel food ingredient) was originating from natural sources. Based on data from France, tomatoes, soups (other than tomato soups) and pasta dishes, and from UK, pasta dishes, tomato sauces and tomato ketchup were the most important natural sources. Based on typical use levels, desserts, including flavoured milk products (~8-22%), non-alcoholic beverages (12-25%) and fine bakery products (4-8%) were the most important sources of lycopene from food colours. In scenarios 5 and 6, the fortified foods were the main contributors to total lycopene. Based on French data, fortified foods accounted for 52% (particularly fruit/vegetable juice-based drinks (19%), fats and dressings (17%), bread (10%)); naturally-occurring lycopene accounted for 31% of the exposure, and desserts, including flavoured milk products, were the most important source of lycopene used as food colour. Based on UK data, fortified foods contributed 40-43% to total lycopene exposure. Bread accounted for approximately 21 to 23% of exposure, and breakfast cereals for 16-17%. Non-alcoholic flavoured drinks contributed 7% to the total lycopene exposure in scenario 5 and 15% in scenario 6.

Overall, the revised exposure assessment of lycopene from both the use as a food colour (at the proposed typical use levels) and the natural occurrence (scenarios 2 to 4) indicated that the potential average exposures for children were approximately of 200 µg/kg bw/day, and around or slightly below

the ADI at the 95th percentile. In adults, the high exposure (95th percentile) to lycopene from use as a food colour and from natural origin was below the ADI.

When exposure to lycopene from fortified foods was also included (scenarios 5 and 6), the exposure was much higher in all populations studied. The mean anticipated exposure in children amounted to 420-500 µg/kg bw/day, and was 44-55% above the ADI, at the 95th percentile. Therefore, EFSA concluded that in this case potential intakes might relatively easily exceed the ADI, particularly for children.

For children, the assessment of the exposure to lycopene from use as a food colour (based on typical use levels) and from natural occurrence (scenarios 1 to 4) based on French and UK data, was considered as the best available accurate estimate, since for these estimates also dilutable drinks, colas and lemonades (e.g. 7-Up) and other clear (uncoloured) beverages, as well as all blackcurrant-containing beverages, were excluded. These estimates are still conservative, because for other foods lycopene as a food colour is assumed to be present in all categories where it is authorised, and it is assumed that a high level consumer will always choose foods coloured red or pink with lycopene.

EFSA noted that all estimates of exposure to lycopene from use as a food colour using typical use levels are based on these conservative assumptions and might overestimate the potential intake.

Compared to the other scenarios, the exposures in scenarios 5 and 6 (taking also into account foods that may contain lycopene as a novel food ingredient) are much higher in all populations studied. These estimates can be considered as especially conservative for the following reasons: lycopene is assumed to be present in all categories where it is authorised, at the maximum permitted level; the food categories mentioned in the terms of reference are very broad and can hardly be refined; foods like bread, fats and dressings, and in some countries also breakfast cereals and fruit/vegetable juice-based drinks (including concentrates), are commonly consumed. Nevertheless, in view of the exposures calculated for scenarios 2 to 4 that are already close to the ADI, it would exceed the ADI with the additional contribution of the foods containing lycopene as a novel food ingredient, particularly for children.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Directive 94/36/EC[4] of the European Parliament and of the Council of 30 June 1994 on colours for use in foodstuffs permits in its Annex V Part 2 the use of the colour E 160d lycopene from red tomatoes in certain foods singly or in combination with some other colours up to maximum levels specified therein.

Following a request from the Commission the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) evaluated the safety of lycopene from two new sources, namely of synthetic lycopene and lycopene from *Blakeslea trispora*. In addition, in view of the re-evaluation of lycopene from tomatoes within the re-evaluation programme of all food colours, EFSA made a global safety assessment of lycopene from all sources.

In its opinion of 30 January 2008, the Panel derived a numerical Acceptable Daily Intake (ADI) of 0.5 mg/kg bw/day for lycopene from all sources. The Panel also concluded that with the uses and actual use levels presented by the applicants, which are lower than the maximum use levels permitted for food colours under Directive 94/36/EC, the intake of lycopene from natural sources and as a food colour would be expected to remain within the ADI of 0.5 mg/kg bw/day. However, this does not hold for the high level intakes by pre-school and school children. The Panel noted that non-alcoholic flavoured drinks were found to be by far the largest potential source in all population groups considered, with percentage contribution of the total calculated intake of lycopene ranging from 66% in male adults to more than 90% in pre-school children. The Panel noted that all exposure estimates to lycopene used as a food colour are based on conservative assumptions because lycopene is assumed to be present in all categories where it is authorised and it is assumed that a high level consumer will always choose foods coloured red or pink with lycopene. EFSA also noted that it does not exclude an occasionally combined high exposure from both natural dietary sources and food colours up to 43 mg of lycopene per day.

The Health and Consumers Directorate-General has subsequently received from the main lycopene producers a report on potential intakes of lycopene by children from use as a food colour and from natural occurrence. This report summarises different scenarios of intake assessments based on several assumptions related to market share data of red coloured beverages, restricted food categories and revised maximum levels of use.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Article 31 of Regulation (EC) No 178/2002[5], the European Commission asks the European Food Safety Authority to provide technical assistance in relation to a revised exposure assessment of lycopene as a food colour in order to support the Commission in the review of the current authorised uses of lycopene in Directive 94/36/EC.

The European Food Safety Authority is asked to carry out a revised exposure assessment of lycopene from use as a food colour and from natural occurrence for adults and children on the basis of the following considerations:

A. All carbonates and ready-to-drink products should be included in the assessment except for those where a red colour would not be appropriate such as colas, clear drinks and blackcurrant

[4] European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs. OJ L 237, 10.9.1994, p. 13.

[5] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1.

flavours. The reasons for exclusion are given in NATCOL's letter of 30 April 2009 under sections A and 2.B and under point 2.2 of the report submitted by NATCOL (Tennant, 2009). The addition of colours to fruit juices is not permitted and therefore fruit juices and nectars should be excluded from the assessment.

B. Dilutable drinks should be excluded from the assessment assuming that lycopene will not be permitted in these products. As dilutable drinks should be considered non-alcoholic flavoured drinks sold in concentrated (or 'dilutable') form to the final consumer, including products sold as 'squashes', 'cordials', etc.

C. Use levels for the remaining non-alcoholic flavoured drinks are either the maximum 12 mg/l or typical levels 5 mg/l. The revised proposed maximum and typical levels of use in other foods are provided in the Table 1 below.

On the basis of the above assumptions, a refined dietary assessment should be made with reference to the one presented in the dietary exposure section of the EFSA opinion, paying a particular attention to high level intakes by pre-school and school children. In particular, the following intake scenarios should be developed:

1) Dietary intake of lycopene from natural occurrence only.

2) Dietary intake of lycopene from natural occurrence and colour uses excluding all non-alcoholic flavoured drinks.

3) Dietary intake of lycopene from natural occurrence and colour uses including selected non-alcoholic flavoured drinks (removing dilutables and drinks that could never contain red colour - see assumptions under A and B above) at 5 mg/l.

4) Dietary intake of lycopene from natural occurrence and colour uses including selected non-alcoholic flavoured drinks (removing dilutables and drinks that could never contain red colour - see assumptions under A and B above) at 12 mg/l.

5) Dietary intake of lycopene from natural occurrence, from uses as a novel food ingredient and colour uses including selected non-alcoholic flavoured drinks (removing dilutables and drinks that could never contain red colour - see assumptions under A and B above) at 5 and 12 mg/l. The list of foods and maximum permitted content of lycopene as a novel food ingredient in accordance with Regulation (EC) No 258/97[6] are given in Table 2 below.

Table 1: Revised proposed maximum levels of use

Foods	Proposed maximum levels of use	Typical use levels as reported by NATCOL

[6] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. OJ L 43, 14.2.1997, p.1.

Non-alcoholic flavoured drinks	12 mg/l	5 mg/l
Candied fruits and vegetables, Mostarda di frutta	30 mg/kg	20 mg/kg
Confectionery	30 mg/kg	10 mg/kg
Decorations and coatings	30 mg/kg	30 mg/kg
Fine bakery wares (e.g. Viennoiserie, biscuits, cakes and wafers)	25 mg/kg	10 mg/kg
Edible ices	40 mg/kg	10 mg/kg
Flavoured processed cheese	5 mg/kg	5 mg/kg
Desserts including flavoured milk products	30 mg/kg	10 mg/kg
Sauces, seasonings (for example, curry powder, tandoori), pickles, relishes, chutney and picalilli	50 mg/kg	15 mg/kg
Jams jellies and marmalades as mentioned in Council Directive 2001/113/EC[7] and similar fruit preparations	10 mg/kg	10 mg/kg
Fish paste and crustacean paste	30 mg/kg	20 mg/kg
Pre-cooked crustaceans	30 mg/kg	20 mg/kg
Salmon substitutes	10 mg/kg	7 mg/kg
Surimi	30 mg/kg	15 mg/kg
Fish roe	30 mg/kg	20 mg/kg
Smoked fish	50 mg/kg	20 mg/kg
Snacks: extruded or expanded savoury snack products	30 mg/kg	15 mg/kg
Snacks: other savoury snack products and savoury coated nuts	30 mg/kg	15 mg/kg
Edible cheese and edible casings	30 mg/kg	20 mg/kg
Complete formulae for weight control intended to replace total daily intake or an individual meal	30 mg/kg	20 mg/kg
Complete formulae and nutritional supplements for use under medical supervision	30 mg/kg	20 mg/kg
Liquid food supplements/dietary integrators	30 mg/kg	20 mg/kg
Solid food supplements/dietary integrators	30 mg/kg	20 mg/kg
Soups	20 mg/kg	10 mg/kg
Meat and fish analogues based on vegetable proteins	30 mg/kg	20 mg/kg
Spirituous beverages (excluding products <15% alcohol by volume) except those mentioned in Annex II or III	30 mg/l	10 mg/l
Aromatized wines, aromatised wine-based drinks and aromatised wine product cocktails as mentioned in Regulation (EEC) No 1601/91[8] except those mentioned in Annex II or III	10 mg/l	10 mg/kg
Fruit wine (still or sparkling); Cider (except cidre bouche) and perry; Aromatised fruit wines, cider, perry	10 mg/l	10 mg/kg

Table 2: List of foods to which lycopene may be added as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

Food category	**Maximum content of lycopene**
Fruit/vegetable juice-based drinks (including concentrates)	2.5 mg/100gr
Drinks intended to meet the expenditure of intense muscular	2.5 mg/100gr

[7] Council Directive 2001/113/EC of 20 December 2001 relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption. OJ L 10, 12.1.2002, p.67.

[8] Council Regulation (EEC) No 1601/91 of 10 June 1991 laying down general rules on the definition, description and presentation of aromatized wines, aromatized wine-based drinks and aromatized wine-product cocktails. OJ L 149, 14.6.1991, p. 1.

effort especially for sportsmen	
Foods intended for use in energy-restricted diets for weight reduction	8 mg/meal replacement
Breakfast cereals	5 mg/100gr
Soups other than tomato soups	1 mg/100gr
Bread (including crispy breads)	3 mg/100gr
Dietary foods for special medical purposes	In accordance with the particular nutritional requirements
Food supplements	15 mg per daily dose as recommended by the manufactures

ASSESSMENT

1. Introduction

Following a request from the European Commission, the European Food Safety Authority (EFSA), carried out a revised exposure assessment of lycopene from use as a food colour and from natural occurrence for children and adults according to a range of conditions presented in the terms of reference. Most of the use levels considered in this revised exposure assessment were reduced considerably compared to those considered in former EFSA evaluations (EFSA, 2008a; 2008b; 2008c; 2008d).

2. Methods

2.1. Occurrence and usage of lycopene

Exposure estimates to lycopene have been performed using the revised maximum and typical use levels as defined in the terms of reference (Table 1), maximum lycopene levels permitted to be added as a novel food ingredient (Table 2) and concentrations of naturally-occurring lycopene in foods (Table 3). Information about the natural occurrence in foods was based on a report by Tennant (2007b). The levels of lycopene in tomatoes, tomato products and food containing lycopene, have been derived by grouping similar foods from the above studies together and taking the arithmetic average. This was to allow for variations in concentration by season and geographical location. Foods that contained only minor amounts of lycopene (less than 0.5 mg/kg), or that were infrequently consumed, were not considered. Furthermore, it is noted that the amount of tomato (products) used in recipes, as well as the percentage of dishes containing tomato or tomato products, might vary considerably.

Table 3: Naturally occurring lycopene levels in food (mg/kg)

Food category	**mg/kg**
	Natural occurrence
Baked beans	3.2
Grapefruit	12.1
Watermelon	46.8
Meat dishes	28.4
Pasta Dishes	69.1
Pizza	32.6
Soup (other than tomato soups)[1]	12.4
Tomato concentrate	584.3
Tomato ketchup	154.6
Tomato canned	77.4
Tomato juice and vegetables juice cocktail tomato juice-based	90.2
Tomato paste/puree	254.3
Tomato raw	54.9
Tomato soup	62
Tomato sun-dried	407.5
Tomato sauce	153
Red sweet sauces (barbecue sauces)	50
Vegetable dishes	31

[1] tomato only as one of various ingredients, for instance in dry or canned vegetable soups

2.2. Food consumption data

Exposure assessments were carried out for children and for adults.

For children, data of the EXPOCHI ("Individual food consumption data and exposure assessment studies for children") consortium were made available. This European project, partly funded by EFSA, is aiming to create a relational network of individual food consumption databases in children, covering different geographical areas within Europe, and to use these data for long-term exposure assessment of food colours and contaminants. EXPOCHI includes 14 national/regional food consumption databases for children in Europe (1-10 years old; except for Cyprus: 11-15 years old) (Huybrechts *et al.,* in preparation). For the present purpose, data from 10 European countries (Belgium, Cyprus, Finland, France, Germany, Greece (Crete), Italy, the Netherlands, Spain and Spain Basque country) were available. These data were derived from 24-hour dietary recalls and dietary records recorded at least on two (non)consecutive days per individual. Information on selected characteristics of the study populations is presented in Annex I. To link food consumption and concentration data in a standardised way, the food consumption data were categorised via use applications listed in Directive 94/36/EC and harmonised with the categories defined in the Flavourings, Additives and Food Contact materials Exposure Task (FACET) project (Huybrechts *et al.*[9], Draft scientific report on long-term dietary exposure to different food colours in young children living in different European countries – prepared within the EXPOCHI project).

According to the EXPOCHI project approach, for the estimation of the long-term exposure, all daily consumption patterns were multiplied with the food colour concentration value per food group, and summed over foods consumed per day per individual. The estimated exposures were adjusted for the individual's body weight.

A distribution of daily exposures, calculated as described above, using mean concentrations per food or food group, includes both the variation between individuals and the variation between the days, for a given individual. However, to assess the long-term intake within a population, only the former type of variation is of interest, since in the long run the variation between different days of one individual will level out. Therefore, to calculate a long-term dietary exposure distribution, the within-person (between days) variation should first be removed from the distribution of daily exposures using statistical models. Ideally, in the EXPOCHI project the relatively new beta binomial-normal (BBN) model (de Boer and van der Voet, 2007; Slob, 2006) should be used. To remove the within-person variation from the daily exposures, the BBN model transforms the daily exposure distribution into a normal distribution using a logarithmic function. After removal of the within-person variation, the normal distribution is back-transformed and is then considered a long-term dietary exposure distribution. However, transformation of the daily exposure distribution into a normal distribution is an important prerequisite to be able to use statistical models that assess the long-term exposure. This prerequisite was not met for the food colours exposure assessment results. Unfortunately, no models are presently available to estimate the long-term exposure on transformed daily exposure distributions that are not normally distributed.

Because the assumption of normality was violated for lycopene, the long-term exposure in the EXPOCHI project was calculated using a simpler approach: all daily exposures are averaged per individual, and the resulting distribution of observed individual means (OIM) is interpreted as the long-term exposure distribution. However, the observed individual means are more variable than the true long-term exposures unless there are many measured days per individual (which is typically not the case). Consequently, high percentiles in the OIM distribution are expected to be conservative (too high) (Huybrechts *et al.,* Scientific report on long-term dietary exposure to different food colours in

[9] The draft scientific report on long-term dietary exposure to different food colours in young children living in different European countries of the EXPOCHI project has been submitted to EFSA on 4 December 2009. The final report is foreseen to be published in the first quarter of 2010.

young children living in different European countries – prepared within the EXPOCHI project – currently under approval).

As the UK is not part of the EXPOCHI consortium, data of the UK National Dietary and Nutrition Survey (NDNS) programme of children were used for pre-school children aged 1.5-4.5 years (Gregory *et al.,* 1995). Detailed individual food consumption data, obtained by a 4-day weighed dietary record method and categorised according to the use applications in Directive 94/36/EC were available from earlier reports provided by the Natural Food Colours Association (NATCOL) (Tennant 2007a,b; Tennant, 2009).

According to an earlier evaluation of lycopene (EFSA, 2008a), non-alcoholic flavoured drinks were identified to be by far the largest potential source in all population groups of lycopene as a colour. Since the UK population is considered to be one of the highest consumers of soft drinks in Europe and as estimates were calculated from more refined adult food consumption data than those currently available to EFSA Panels (e.g. EFSA Concise European Food Consumption Database, which gives aggregate food categories consumed in 19 European countries (EFSA, 2008e)) it was decided to select the UK population as representative of the EU consumers for the lycopene estimates for adults. Detailed individual food consumption data, obtained by a 7-day weighed dietary record method of subjects aged 19-64 years (Henderson *et al.,* 2002) and categorised via the use applications listed in Directive 94/36/EC were available from an earlier report provided by NATCOL (Tennant, 2007a,b).

2.3. Calculations

The exposure to lycopene was assessed using a stepwise approach for a large range of scenarios (see terms of reference). For clarity reasons scenario 5 as defined in the terms of reference was replaced by two different scenarios: scenario 5 and scenario 6. Scenario 5 now refers to the dietary intake of lycopene from natural occurrence, from uses as a novel food ingredient and colour uses including selected non-alcoholic flavoured drinks (removing dilutables and drinks that could never contain red colour - see assumptions under A and B in the terms of reference) at 5 mg/l, whereas scenario 6 is the same as scenario 5 with only a use level of 12 mg/l for selected non-alcoholic flavoured drinks.

First, the exposure to lycopene was assessed using the revised maximum use levels for a range of scenarios (see above).

The estimates were further refined using typical use levels of lycopene as a food colour for scenario 2 to 4 (see above). For scenarios 5 and 6, the estimates have been calculated using typical use levels for the use as food colour and maximum permitted use levels for fortified food (Table 2). Most of these estimates are based on intake distributions. Where possible, refinements in the food categorisation were made.

Annex I presents an overview of the different foods and food categories that were taken into account, and the usage levels of lycopene per scenario.

2.3.1. Calculations based on maximum use levels

Exposure estimates for children (1-10 years old) were calculated by EFSA using mean food consumption data (total population) and the high level consumption of foods (users only) provided by the EXPOCHI consortium. Except for France, it appeared that the information on foods used in the EXPOCHI project, as well as the food grouping, was not detailed enough to distinguish the consumption of foods naturally containing lycopene. For the same reason most countries were not able to distinguish dilutables and drinks that could never contain red colour. Therefore, only exposure

assessments for five scenarios (number 2-6) are available for the EXPOCHI countries and the consumption of non-alcoholic flavoured drinks often represents all types of soft drinks.

For UK children, mean consumption data of foods which contain naturally-occurring lycopene and foods that may contain lycopene as food colour were available (Tennant, 2009).To assess the intake from foods that may contain lycopene as a novel food ingredient, further named fortified foods, information of the mean (survey population) and high level consumption (consumers only) of this type of foods (Table 3) was added using other reports (Tennant, 2006; Tennant, 2007a,b; Gregory *et al.,* 1995). The data did not allow a further refinement, and therefore it was assumed that all foods belonging to these categories were fortified. For bread, the high level consumption was not available. In the report of the Scientific Cooperation (SCOOP) Task 4.2 (EC, 1998), a factor varying from 2.5 to nearly 3.5 was observed between mean consumption and high level consumption of four types of food (no information on bread). In the EXPOCHI databases the high level consumption was 2 to 3.7 times the average bread consumption. Therefore, for the present calculations it was assumed that for UK consumers only, the 95th percentile was 3.5 times the average consumption of bread.

In addition to the French EXPOCHI data, France also provided data on the consumption of foods naturally containing lycopene. Moreover, where possible, the consumption of some food categories was refined (e.g. removing non-alcoholic flavoured drinks that could never contain lycopene; removing home-made bread etc.).

For children, the data from EXPOCHI countries, the UK data and the additional French data were used to calculate the mean and high level exposure to lycopene using revised maximum use levels. High level exposure (95th percentile) was based on the assumption that an individual might be a high level consumer of one food category and would be an average consumer of the others. This approach has been tested using a computer analysis based on EXPOCHI data to estimate the high level exposure (95th percentile) and on calculations using 2 models. The first model was based on the assumption described above. The calculation was as follows: Estimated high level intake = the sum of the highest intake (consumers only) + mean population intakes from rest of the diet. In the other model the estimated high level intake was based on the sum of the two highest intakes (consumers only) + mean population intakes from rest of the diet (SCOOP Task 4.2 (EC, 1998)). It appeared that for the present purpose the first model was more in agreement with the intakes figures obtained by computer analysis. Therefore, this approach was preferred for the calculations based on the maximum proposed use levels in order to avoid excessively conservative estimates.

For adults, mean and high level exposure was calculated using available UK consumption data of foods naturally containing lycopene, foods that may contain lycopene as a colour and fortified foods (Tennant, 2006; Tennant 2007a,b; Henderson *et al.,* 2002). No information was available to adjust non-alcoholic flavoured drinks or to refine fortified foods. As mentioned above, the high level consumption of bread for consumers was based on 3.5 times the average consumption.

2.3.2. Calculations based on typical use levels

The estimates for children (1-10 years old) have been performed by the EXPOCHI consortium (Huybrechts *et al.,* in preparation) based on detailed individual data and intake distributions. As mentioned in paragraph 2.3.1, exposure estimates for scenario 1 could not be carried out and the calculations of the other scenarios did not include lycopene from natural occurrence. Furthermore, most countries could not make appropriate adjustments for non-alcoholic drinks.

For UK children (aged 1.5-4.5 years) estimates of lycopene and lycopene from natural occurrence and colour uses for scenario 1 to 4 were based on already available assessments using detailed individual consumption data (UK NDNS, 1992-1993) and the same typical use levels as presented in Table 1 (Tennant, 2009). Non-alcoholic beverages were considered after exclusion of dilutable drinks, colas

and lemonades (e.g. 7-up) and other clear (uncoloured) beverages, as well as all blackcurrant-containing beverages. To be able to perform scenarios 5 and 6, the mean and high consumption of particular foods were added (see paragraph 3.1.1). This implies, however, that in contrast to the calculations for scenarios 1 to 4, the assessment of the high level exposure could not be based on the intake distribution. For scenarios 5 and 6 high level exposure (95th percentile) to lycopene was calculated by the sum of the highest intake (consumers only) and the mean population intakes from rest of the diet (see above).

In addition to the French EXPOCHI estimates, France also made an assessment based on individual food consumption data, including food naturally containing lycopene, using intake distributions. Moreover, where possible, the consumption was adjusted (see paragraph 2.3.1).

Estimates of lycopene from natural occurrence and from colour uses for the adult population were based on already available individual food consumption UK data (19-64 years; UK NDNS, 2000-2001) and typical use levels (Tennant, 2007a,b). The consumption of non-alcoholic flavoured drinks was not adjusted. For the calculations of scenarios 5 and 6, the procedures were the same as mentioned for the UK children.

3. Exposure results

3.1. Potential exposures based on revised maximum use levels

Table 4 summarises the anticipated exposure of children to lycopene considering revised maximum use levels. Mean dietary exposure of European children (aged 10 years and weighing 18-29 kg) considered by the EXPOCHI consortium ranged from 81 to 347 µg/kg bw/day for scenario 2, from 86 to 471 µg/kg bw/day for scenario 3 and from 93 to 535 µg/kg bw/day for scenario 4. When fortified foods were taken into account, the mean potential exposure was much higher and ranged from 363 to 832 µg/kg bw/day for scenario 5 and from 370 to 897 µg/kg bw/day for scenario 6. At the 95th percentile the values increased from 185 to 1190 µg/kg bw/day (scenario 2) to 401-1663 µg/kg bw/day (scenario 6).

Data from Cyprus for children aged 11-15 years illustrate that older children had lower exposure per kg bw. The mean body weight of these children was 51 kg.

Table 4: Exposure to lycopene (µg/kg bw/day) in children aged 1-10 years from use as a food colour and from lycopene to be added as a novel food ingredient, based on maximum proposed use levels[1]

	Scenario 1		Scenario 2		Scenario 3		Scenario 4		Scenario 5		Scenario 6	
	(µg/kg bw/day)											
	Mean	95th percentile	Mean	95th percentile	Mean	95th percentile	Mean	95th percentile	Mean	95th percentile	Mean	95th percentile
BE	-[5]	-	347	951	381	985	429	1033	823	1425	871	1473
CY[2]	-	-	66	309	72	315	80	323	200	393	208	401
GR	-	-	116	457	123	464	133	474	350	795	360	805
DE[3]	-	-	289	794	319	824	360	866	682	1249	723	1291
FI	-	-	204	485	229	510	264	545	455	736	490	771
FR	-	-	188	486	205	503	228	526	419	717	443	741
IT	-	-	85	185	90	191	97	198	378	571	385	579
NL	-	-	424	1190	471	1236	535	1301	832	1598	897	1663
SP	-	-	81	178	86	183	93	190	363	549	370	556
SP[4]	-	-	200	478	206	484	214	493	484	762	492	771

[1]Excluding lycopene from natural occurrence; [2]Aged 11-15 years; [3]Data refer to the 2007 database (exposure in 2006 and 2008 slightly lower); [4]Basque Country; [5]Not applicable

Exposure estimates including naturally-occurring lycopene in French children show that mean anticipated exposures were approximately 300 µg/kg bw/day for scenarios 2, 3 and 4 and approximately 510 µg/kg bw/day for the scenarios which included foods which may be fortified (Table 5). For young children in UK, mean anticipated exposure ranged from 374 µg/kg bw/day (scenario 2) to 452 µg/kg bw/day (scenario 4) and from 606 to 651 µg/kg bw/day for scenario 5 and 6, respectively. At the 95th percentile, the potential exposure increased in French children from approximately 600 (scenario 2) to 813 µg/kg bw/day (scenario 6). In UK children, potential exposure ranged from 626 µg/kg bw/day (scenario 2) to 915 µg/kg bw/day (scenario 6) (Table 5).

Table 5: Exposure to total lycopene (µg/kg bw/day) based on maximum proposed use level

	Scenario 1		Scenario 2		Scenario 3		Scenario 4		Scenario 5		Scenario 6	
	(µg/kg bw/day)											
	Mean	95th percentile	Mean	95th percentile	Mean	95th percentile	Mean	95th percentile	Mean	95th percentile	Mean	95th percentile
Childre n												
FR	131	322	301	601	302	602	304	603	511	811	513	813
UK	140	440	374	626	407	658	452	702	606	897	651	915
Adults												
UK	84	300[1]	144	348	159	364	180	327	242	395	263	416

[1] 97.5th percentile

According to Table 5, the anticipated exposures of adults to lycopene, including naturally-occurring lycopene, ranged from 144 µg/kg bw/day (scenario 2) to 263 µg/kg bw/day (scenario 6) at the mean level and from 348 µg/kg bw/day (scenario 2) to 416 µg/kg bw/day (scenario 6) at the 95th percentile.

3.2. Potential exposures based on typical use levels

Table 6 presents exposure estimates considering the typical use levels from Table 1. Mean potential exposure of European children considered by the EXPOCHI consortium and aged 1-10 years increased from 36-152 µg/kg bw/day (scenario 2) to 47-264 µg/kg bw/day (scenario 4). Taking into account also fortified foods, the mean potential exposure varied between 167 and 624 µg/kg bw/day and 176 and 673 µg/kg bw/day in scenario 5 and 6, respectively. At the 95th percentile, potential exposures ranged from 90-362 µg/kg bw/day to 117-582 µg/kg bw/day for scenarios 2 and 4, respectively, and reached 516-1674 µg/kg bw/day in scenario 6.

Table 6: Exposure to total lycopene (µg/kg bw/day) based on typical use levels

	Scenario 1		**Scenario 2**		**Scenario 3**		**Scenario 4**		**Scenario 5***		**Scenario 6***	
	(µg/kg bw/day)											
	Mean	95th percentile	Mean	95th percentile	Mean	95th percentile	Mean	95th percentile	Mean	95th percentile	Mean	95th percentile
BE[1]	NA[5]	NA	131	325	166	394	215	514	624	1249	673	1369
CY[1,2]	NA	NA	26	75	32	86	40	130	167	363	176	380
GR[1]	NA	NA	44	106	52	127	62	163	285	904	295	598
DE[1,3]	NA	NA	142	463	169	493	207	572	559	1638	597	1674
FI[1]	NA	NA	79	153	104	202	139	282	334	585	327	516
FR[1]	NA	NA	77	164	94	198	118	259	319	691	344	642
IT[1]	NA	NA	36	90	41	99	47	117	347	724	353	724
NL[1]	NA	NA	152	362	198	412	264	582	571	1041	637	1136
SP[1]	NA	NA	70	193	91	244	121	329	323	598	353	656
SP[1,4]	NA	NA	79	186	85	200	93	224	375	683	384	685
Children												
FR	131	322	199	411	200	411	202	417	422	775	423	775
UK	140	440	180	480	190	500	210	520	458	722[8]	503	767[8]
Adults												
UK	84	300[6]	102	307	118	322	139	285	201	353[8]	222	375[8]

* For scenarios 5 and 6, the estimates have been calculated using typical use levels for the use as food colour and maximum permitted use levels for fortified food.

[1]Excluding lycopene from natural occurrence; [2]Aged 11-15 years; [3]Data refer to the 2007 database (exposure in 2006 and 2008 slightly lower); [4]Basque Country; [5]Not Applicable; [6]97.5th percentile; [8]Calculated values

Intake of naturally-occurring lycopene was 131 µg/kg bw/day and 140 µg/kg bw/day at the mean, and 322 µg/kg bw/day and 440 µg/kg bw/day at the 95th percentile in French and UK children, respectively.

In French children, anticipated exposure estimates based on typical use levels and including naturally-occurring lycopene were approximately 200 µg/kg bw/day (mean) and 411-417 µg/kg bw/day (95th percentile) excluding foods that may be fortified (scenarios 2 to 4), and approximately 423 µg/kg bw/day (mean) and 775 µg/kg bw/day (95th percentile) when potential fortified foods were included (scenarios 5 and 6). In UK children, the anticipated exposure ranged from 180 µg/kg bw/day (mean) and 480 µg/kg bw/day (95th percentile) (scenario 2) to 210 µg/kg bw/day (mean) and 520 µg/kg bw/day (95th percentile) (scenario 4), whereas the potential exposure increased to approximately 500 µg/kg bw/day (mean) and nearly 770 µg/kg bw/day (95th percentile) after adding foods that may be fortified (Table 6).

In UK adults, the estimated intake of naturally-occurring lycopene was 84 µg/kg bw/day at the mean level and 300 µg/kg bw/day at the high level (97.5th percentile). According to the different scenarios, the anticipated exposures of adults to lycopene, including naturally-occurring lycopene and considering typical use levels, ranged from 102 µg/kg bw/day (scenario 2) to 222 µg/kg bw/day (scenario 6) at the mean level, and from 307 µg/kg bw/day (scenario 2) to 375 µg/kg bw/day (scenario 6) at the 95th percentile (Table 6).

3.2.1. Sources of lycopene

In the scenarios calculated using typical use levels and the EXPOCHI data, i.e. exposure estimates excluding naturally-occurring lycopene, main contributors to the exposure to lycopene (≥10% in all countries) in scenario 2 were desserts, including flavoured milk products, and fine bakery wares (Table 7). Together with non-alcoholic flavoured drinks, these food categories were also important lycopene sources in scenarios 3 and 4. In scenario 5, foods that may be fortified accounted for 65 to 89% of exposure (fruit/vegetable juice-based drinks 11 to 41%; bread 15 to 31%). Desserts, including flavoured milk products accounted for more than 10% in seven countries. Also in scenario 6, fortified foods were by far the most important contributor (65 to 87%). In six countries, more than 10% of exposure was derived from non-alcoholic flavoured drinks, whereas desserts, including milk flavoured products, were also an important source in seven countries.

Table 7: Food groups contributing to potential exposure to lycopene as food colour (≥ 10%) in 10 European countries and number of countries with a lower contribution

	Food categories	**% contribution**	**# countries with contribution <10%**
Scenario 2	Fine bakery wares	11.3-50.5	-
	Desserts including flavoured milk products	32.3-70.4	-
Scenario 3	Non-alcoholic flavoured drinks	11.9-23.9	1
	Fine bakery wares	11.7-44.5	1
	Desserts including flavoured milk products	27.2-62.4	-
Scenario 4	Non-alcoholic flavoured drinks	15.7-42.9	-
	Fine bakery wares	10.1-38.8	2
	Desserts including flavoured milk products	22.2-56.7	-
Scenario 5	Desserts including flavoured milk products	10.8-17.8	3
	Fruit/vegetable juice-based drinks (including concentrates)	11.2-41.4	-
	Fats and dressing	10.3-36.4	2
	Bread (including crisp bread)	15.1-29.7	-
Scenario 6	Non-alcoholic flavoured drinks	10.8-17.6	4
	Desserts including flavoured milk products	10.3-13.3	3
	Fruit/vegetable juice-based drinks (including concentrates)	10.3-39.3	-
	Fats and dressing	11.4-35.7	3
	Bread (including crisp bread)	14.0-29.7	-

When naturally-occurring lycopene was included in the different estimates in French children, about 65% of exposure in scenario 2, 3 and 4 came from this natural source, with tomatoes, soups (other than tomato soups) and pasta dishes as the most important foods. Other important contributors in scenarios 2, 3 and 4 were desserts, including flavoured milk products (~22%) and fine bakery wares (~8%). In scenarios 5 and 6, naturally-occurring lycopene accounted for 31% of the exposure, fortified foods for 52% (particularly fruit/vegetable juice-based drinks (19%), fats and dressings (17%), bread (10%)). Desserts, including flavoured milk products, accounted for 10% of exposure. In UK children, naturally-occurring lycopene contributed 65% of the total lycopene exposure in scenario 2, 57% in scenario 3, 49% in scenario 4, and 33 and 31% in scenario 5 and 6, respectively. Pasta dishes, tomato

sauces and tomato ketchup were the most important contributors to the exposure to naturally-occurring lycopene. In scenario 2, desserts, including flavoured milk products contributed 11%; all other food categories contributed less than 10%. In scenario 3, non-alcoholic flavoured drinks and desserts, including flavoured milk products contributed 12% and 10%, respectively. In scenario 4, these food categories contributed 25% and 8%. Fortified foods were the main contributors in scenarios 5 (43%) and 6 (40%). Bread accounted for approximately 21 to 23% of exposure, and breakfast cereals for 16-17%. Non-alcoholic flavoured drinks contributed 7% to total lycopene exposure in scenario 5 and 15% in scenario 6.

4. Discussion

Several food consumption databases were used to conduct the current exposure assessment. The data of the EXPOCHI project present a good geographical spread of the food consumption of children in Europe, a standardised approach in food categorisation via use applications in Directive 94/36/EC and in executing exposure assessments. However, the different food consumption databases used within the EXPOCHI project were based on different survey designs using different dietary assessment methods, and although the highest level of detail possible was provided, this level differed for the various countries. In the food consumption databases there was insufficient detail in most food descriptors at the time of the project to be able to make very detailed food selections, necessary for the calculations of naturally-occurring lycopene and drinks that could never be coloured with lycopene.

In reviewing the results, it is important to note that the exposure to naturally-occurring lycopene and the total lycopene exposure could not be calculated for EXPOCHI countries. Estimates for scenarios 2 to 6 were carried out, but since the exposure to naturally-occurring lycopene is not taken into account, the potential exposure is underestimated. On the other hand, the exposure to lycopene from use as a food colour and from fortified foods can be considered as very conservative since it was assumed that all foods belonging to specific food categories are coloured with lycopene. Adjustments for dilutables and beverages never containing lycopene in UK and French data indicate that a considerable proportion (~65-95%) of the drinks was removed.

Despite the limitations for the present assessment, EXPOCHI data are the best available data to give insight into differences in exposure to lycopene from colours and fortified foods between European countries, and in lycopene sources. The data suggest that lower exposure levels to added lycopene were observed in South European countries (particularly Spain and Italy) and the highest exposure levels in the Netherlands, Belgium and Germany. Differences in consumption patterns, for instance regarding non-alcoholic flavoured drinks and desserts, can partly explain this observation. Conversely, *per capita* intakes based on Food balance sheets (FAOSTAT) and DAFNE European data (http://www.nut.uoa.gr/dafnesoftweb) indicate that the intake of naturally-occurring lycopene (i.e. lycopene from natural sources) is higher in Southern countries. This could mean that the actual differences in exposure to total lycopene are smaller than suggested in the present estimates.

It is also noteworthy that age ranges available in the different EXPOCHI databases varied. In Belgium and the Netherlands children were 2-6 years old with a mean body weight of approximately 18 kg. In Germany, children aged 1-10 years were included, weighing approximately 20 kg on average. In most South European countries, children were between 3 and 10 years, and the average body weight varied between 25 and 30 kg. These differences also affect the differences in exposure expressed per kg bw.

For children, only additional estimates from France and available UK data could be used to assess the exposure to lycopene from use as a food colour and from natural occurrence for children. Since for these estimates also dilutable drinks, colas and lemonades (e.g. 7-Up) and other clear (uncoloured) beverages, as well as all blackcurrant containing beverages were excluded, the estimates for scenarios 1 to 4 can be considered as the best available accurate intakes. Using typical use levels in both countries, the mean exposure is in the same range (~200 µg/kg bw/day). At the 95th percentile,

exposure to total lycopene in UK children is around or slightly above the current ADI (0.5 mg/kg bw/day) and in French children the high level estimates for scenarios 1 to 4 are between 410 and 420 µg/kg bw/day, and thus slightly below the ADI. It is noted that French children are older (3-10 years compared to 1.5-4.5 years for UK children) and have a higher body weight (25 kg versus 14.5 kg).

Results for adults also present the total lycopene exposure, including naturally-occurring lycopene. Despite the fact that in the calculations no adjustments were made for non-alcoholic flavoured drinks in scenarios 2-4, the exposure at the 95th percentile is below the ADI.

Typical use levels are considered to represent the most common applications, whereas maximum use levels for lycopene will only be used when an intense colour shade is required (Tennant, 2009).

It was noted that the estimates of exposure to lycopene from use as a food colour using typical use levels might overestimate the potential intake because they are based on conservative assumptions: lycopene is assumed to be present in all categories where it is authorised and it is assumed that a high level consumer will always choose foods coloured red or pink with lycopene.

About 50 to 65% of the total exposure to lycopene (excluding lycopene added as a novel food ingredient) was from natural sources. The estimates also indicated that based on typical use levels, desserts, including flavoured milk products, non-alcoholic beverages and fine bakery products are the most important sources of lycopene from food colours.

Compared to all other scenarios, the exposures in scenarios 5 and 6 are much higher in all populations studied. In these calculations, foods that may contain lycopene as a novel food ingredient are taken into account. These estimates can be considered as especially conservative for the following reasons: lycopene is assumed to be present in all categories where it is authorised, at the maximum permitted level; the food categories mentioned in the terms of reference are very broad and can hardly be refined; foods like bread, fats and dressings, and in some countries also breakfast cereals and fruit/vegetable juice-based drinks (including concentrates), are commonly consumed. Nevertheless, in view of the exposures calculated for scenarios 2 to 4 that are already close to the ADI, it would be relatively easy to exceed the ADI, with the additional contribution of the foods containing lycopene as a novel food ingredient, particularly for children.

CONCLUSIONS

Following a request from the Commission a revised exposure assessment of lycopene from its use as a food colour and from natural occurrence, for children and adults, was carried out using revised maximum and typical use levels according to a range of scenarios defined in the terms of reference, and with reference to the exposure assessment presented in the former opinion on lycopene by the EFSA's AFC Panel. EFSA noted that most of the use levels were reduced considerably compared to those considered in former EFSA evaluations.

In French and UK children, the intake of lycopene from natural sources (naturally-occurring lycopene - scenario 1) was 131 and 140 µg/kg bw/day at the mean and 322 and 440 µg/kg bw/day at the 95th percentile, respectively.

Overall, the revised exposure assessment of lycopene from both the use as a food colour (at the proposed typical use levels) and the natural occurrence (scenarios 2 to 4) indicates that the potential average exposures for children were approximately of 200 µg/kg bw/day and around or slightly below the ADI at the 95th percentile. In adults, the high exposure to lycopene from use as a food colour and from natural origin was below the ADI.

When exposure to lycopene from fortified foods was also included (scenarios 5 and 6); the exposure was much higher in all populations studied. The mean anticipated exposure in children amounted to 420-500 µg/kg bw/day and the high level exposure was 44-55% above the ADI. In view of the exposures already close to the ADI calculated for the other scenarios, EFSA concluded that in this case, potential intakes might relatively easily exceed the ADI, particularly for children.

DOCUMENTATION PROVIDED TO EFSA

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ANNEXES

ANNEX 1

Concentrations of lycopene (mg/kg or mg/l) used in different scenarios

	Food category	Scenario 1	Scenario 2		Scenario 3		Scenario 4		Scenario 5		Scenario 6	
		Natural occurrence	Maximum level	Typical level	Maximum level	Typical level	Maximum level	Typical level	Maximum level	Typical level	Maximum level	Typical level
Natural source	Baked beans	3.2	3.2	3.2	3.2	3.2	3.2	3.2	3.2	3.2	3.2	3.2
	Grapefruit	12.1	12.1	12.1	12.1	12.1	12.1	12.1	12.1	12.1	12.1	12.1
	Watermelon	46.8	46.8	46.8	46.8	46.8	46.8	46.8	46.8	46.8	46.8	46.8
	Meat dishes	28.4	28.4	28.4	28.4	28.4	28.4	28.4	28.4	28.4	28.4	28.4
	Pasta Dishes	69.1	69.1	69.1	69.1	69.1	69.1	69.1	69.1	69.1	69.1	69.1
	Pizza	32.6	32.6	32.6	32.6	32.6	32.6	32.6	32.6	32.6	32.6	32.6
	Soup (other than tomato soups)	12.4	12.4	12.4	12.4	12.4	12.4	12.4	12.4	12.4	12.4	12.4
	Tomato concentrate	584.3	584.3	584.3	584.3	584.3	584.3	584.3	584.3	584.3	584.3	584.3
	Tomato ketchup	154.6	154.6	154.6	154.6	154.6	154.6	154.6	154.6	154.6	154.6	154.6
	Tomato canned	77.4	77.4	77.4	77.4	77.4	77.4	77.4	77.4	77.4	77.4	77.4
	Tomato juice and vegetables juice cocktail tomato juice-based	90.2	90.2	90.2	90.2	90.2	90.2	90.2	90.2	90.2	90.2	90.2
	Tomato paste/puree	254.3	254.3	254.3	254.3	254.3	254.3	254.3	254.3	254.3	254.3	254.3
	Tomato raw	54.9	54.9	54.9	54.9	54.9	54.9	54.9	54.9	54.9	54.9	54.9
	Tomato soup	62	62	62	62	62	62	62	62	62	62	62
	Tomato sun-dried	407.5	407.5	407.5	407.5	407.5	407.5	407.5	407.5	407.5	407.5	407.5
	Tomato sauce	153	153	153	153	153	153	153	153	153	153	153
	Red sweet sauces (barbecue sauces)	50	50	50	50	50	50	50	50	50	50	50
	Vegetable dishes	31	31	31	31	31	31	31	31	31	31	31
Food colour	Non-alcoholic flavoured drinks	n.a.	0	0	5	5	12	12	5	5	12	12
	Candied fruits and vegetables. Mostarda di frutta	n.a.	30	20	30	20	30	20	30	20	30	20
	Confectionery	n.a.	30	10	30	10	30	10	30	10	30	10
	Decorations and coatings	n.a.	30	30	30	30	30	30	30	30	30	30
	Fine bakery wares (e.g. Viennoiserie, Biscuits, cakes and wafers)	n.a.	25	10	25	10	25	10	25	10	25	10

	Edible ices	n.a.	40	10	40	10	40	10	40	10	40	10
	Flavoured processed cheese	n.a.	5	5	5	5	5	5	5	5	5	5
	Desserts including flavoured milk products	n.a.	30	10	30	10	30	10	30	10	30	10
	Sauces, Seasonings (for example curry powder, tandoori), pickles, Relishes, chutney and picalilli	n.a.	50	15	50	15	50	15	50	15	50	15
	Jams jellies and marmalades as mentioned in Council Directive 2001/113/EC and similar fruit preparations	n.a.	10	10	10	10	10	10	10	10	10	10
	Fish paste and crustacean paste	n.a.	30	20	30	20	30	20	30	20	30	20
	Pre-cooked crustaceans	n.a.	30	20	30	20	30	20	30	20	30	20
	Salmon substitutes	n.a.	10	7	10	7	10	7	10	7	10	7
	Surimi	n.a.	30	15	30	15	30	15	30	15	30	15
	Fish roe	n.a.	30	20	30	20	30	20	30	20	30	20
	Smoked fish	n.a.	50	20	50	20	50	20	50	20	50	20
	Snacks: extruded or expanded savoury snack products	n.a.	30	15	30	15	30	15	30	15	30	15
	Snacks: other savoury snack products and savoury coated nuts	n.a.	30	15	30	15	30	15	30	15	30	15
	Edible cheese and edible casings	n.a.		20		20		20		20		20
	Complete formulae for weight control intended to replace total daily intake or an individual meal	n.a.	30	20	30	20	30	20	30	20	30	20
	Complete formulae and nutritional supplements for use under medical supervision	n.a.	30	20	30	20	30	20	30	20	30	20
	Liquid food supplements/ dietary integrators	n.a.	30	20	30	20	30	20	30	20	30	20
	Solid food supplements/dietary integrators	n.a.	30	20	30	20	30	20	30	20	30	20
	Meat and fish analogues based on vegetable proteins	n.a.	30	20	30	20	30	20	30	20	30	20
	Spirituous beverages (excluding products <15% alcohol by volume) except those mentioned in Annex II or III	n.a.	30	10	30	10	30	10	30	10	30	10
	Aromatized wines. aromatized wine based drinks and aromatized wine product cocktails as mentioned in Regulation (EEC) No 1601/91 except those mentioned in Annex II or III	n.a.	10	10	10	10	10	10	10	10	10	10

	Fruit wine (still or sparkling); Cider (except cidre bouche) and perry; Aromatized fruit wines, cider, perry	n.a.	10	10	10	10	10	10	10	10	10	10
	Fruit/vegetable juice-based drinks (including concentrates)	n.a.	0	0	0	0	0	0	25	25	25	25
Novel food ingredient	Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen	n.a.	0	0	0	0	0	0	25	25	25	25
	Breakfast cereals	n.a.	0	0	0	0	0	0	50	50	50	50
	Fats and dressings	n.a.	0	0	0	0	0	0	100	100	100	100
	Bread (including crispy breads)	n.a.	0	0	0	0	0	0	30	30	30	30

n.a. = not applicable

ANNEX 2

Selected characteristics of study populations

Country	Age (years)	N	Body weight (kg)	Dietary method	Reference
Belgium	2-6	661	17.65	3-day record	Huybrechts *et al.*, 2008
Cyprus	12-14	268	51.11	3-day record	
Greece	4-6	795	22.41	3-day record	Linardakis *et al.*, 2008 (sampling procedures)
Germany[1]	1-10	311	20.66	3-day weighed record	Kersting *et al.*, 2004 Kroke *et al.*, 2004 Sichtert-Hellert *et al.*, 1999; 2000; 2004
Finland	7-8	250	27.96	4-day record	Simell O *et al.*, 2009
France	3-10	574	25.11	7-day record	AFFSA report, 2009
Italy	1-10	252	25.17	3-day record	Leclercq *et al.*, 2009
Netherlands	2-6	1279	18.3	2 x 24-hour recall	Ocké *et al.*, 2008
Spain	1-10	382	29.06	2 x 24-hour recall	Larrañaga *et al.*, 2006
Spain[2]	4-10	760	26.18	2x 24-hour recall	Serra-Majem *et al.*, 2001
United Kingdom					
Children	1.5-4.5	1717	14.5	4-day weighed record	Gregory *et al.*, 1995
Adults	19-64	1724	60[3]	7-day weighed record	Henderson *et al.*, 2002

[1] Data refer to the 2007 database (exposure in 2006 and 2008 slightly lower)
[2] Basque Country Spain
[3] standard body weight

GLOSSARY AND ABBREVIATIONS

ADI	Acceptable Daily Intake
AFC	Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food
ANS	Panel on Food Additives and Nutrient Sources added to Foods
BBN	beta binomial-normal
bw	body weight
DAFNE	Data Food Networking
EC	European Commission
EFSA	European Food Safety Authority
EXPOCHI	Individual food consumption data and exposure assessment studies for children
FACET	Flavourings, Additives and Food Contact materials Exposure Task project
FAOSTAT	Food and Agriculture Organisation Statistics
NATCOL	Natural Food Colours Association
NDNS	UK National Dietary and Nutrition Survey
OIM	observed individual means