# Maximum levels proposed for the addition of beta-carotene to foods including food supplements

The accompanying main opinion "**Updated recommended maximum levels for the addition of vitamins and minerals to food supplements and conventional foods**" can be found here: https://www.bfr.bund.de/cm/349/updated-recommended-maximum-levels-for-the-addition-of-vitamins-and-minerals-to-food-supplements-and-conventional-foods.pdf

## 1 Results

The German Federal Institute for Risk Assessment (BfR) recommends a maximum level for the addition of β-carotene to food supplements of 3.5 milligrams (mg) β-carotene per daily recommended dose of a food supplement (Table 1).

**Table 1: Proposed maximum levels**

| Food category | Maximum level |
|---|---|
| Food supplements (per daily recommended dose of an individual product) | 3.5 mg |

Based on the assumption of a saturated market with regard to conventional fortified foods (30 % of the daily energy intake comes from fortified foods), the derivation procedure resulted in insignificant fortification amounts for the addition of β-carotene to beverages. In view of that, the BfR proposes the following options:

Option 1: Assuming that the market is - and remains - only partially saturated would result in a maximum level of 1.7 mg/100 g for solid food and of 0.45 mg/100 millilitres (ml) for beverages. The level of protection under this option would be lower than under the assumption of a saturated market.

Option 2: Restricting the addition of β-carotene for nutritional purposes to the three food groups 'breakfast cereals', 'dairy products' and 'juices and soft drinks' and setting a maximum level corresponding to 15 % and 7.5 % of the nutrition labelling reference value for these three groups, i.e. 0.72 mg/100 g for solid foods and 0.36 mg/100 ml for juices and soft drinks.

Option 3: Restricting the addition of β-carotene for nutritional purposes to solid foods.

## 2 Rationale

### 2.1 Tolerable Upper Intake Level[1] (UL) and Dietary Reference Value

In view of the unexpected negative results from controlled studies with β-carotene supplements (increase in lung cancer rate and mortality in smokers and persons working with asbestos), the former Scientific Committee on Food (SCF) of the European Commission had withdrawn the ADI value (Acceptable Daily Intake) for β-carotene of 5 milligrams per kilogram

[1] Tolerable Upper Intake Level = Maximum level of total chronic daily intake of a nutrient (from all sources) judged to be unlikely to pose a risk of adverse health effects to humans.

body weight (mg/kg bw) in 2000 and advised caution in the use of β-carotene in isolated form. As no dose-response relationship could be derived from the available data and information on specific effects of individual β-carotene isomers was lacking, no UL could be derived for β-carotene (SCF, 2000).

A more recent assessment by the Panel on Food Additives and Nutrient Sources Added to Food (ANS Panel) of the European Food Safety Authority (EFSA) also concluded that the data base is still insufficient to derive an ADI for mixed carotenoids and β-carotene. However, for the use of (synthetic) β-carotene and for β-carotene from palm oil, carrots and seaweed, the ANS Panel considered that there were no safety concerns, provided the intake from this use as a food additive and as food supplement, did not amount to more than the amount likely to be ingested from the regular consumption of the foods in which they occur naturally (5-10 mg/day)[2] (EFSA, 2012a). In another EFSA opinion, the Panel concluded that exposure to β-carotene from its use as food additive and as food supplement at a level below 15 mg/day does not give rise to concerns about adverse health effects in the general population, including heavy smokers (EFSA, 2012b; Table 2).

The intake level of 15 mg/day proposed by EFSA as acceptable (2012a and b) for supplemental β-carotene intake does not have the same scientific quality as a UL. The EFSA value was derived mainly on the basis of a meta-analysis by Druesne-Pecollo et al. (2010), in which the authors concluded that data from controlled intervention studies indicated an increased risk of lung cancer and stomach cancer after supplementation of 20-30 mg/day for five to seven years in people who smoked and worked with asbestos. A dose of 20 mg/day could therefore be considered a LOAEL (Lowest Observed Adverse Effect Level; lowest experimental dose at which there was an observed adverse effect on health). However, based on the available data, a NOAEL (No Observed Adverse Effect Level; highest experimental dose at which there was no observed adverse effect on health) could not be defined and a UL not be derived.

The BfR points out that the Norwegian Scientific Committee for Food Safety (VKM) has classified a daily intake of 20 mg as LOAEL on the basis of the available data from the ATBC study (Alpha-Tocopherol Beta-Carotene Cancer Prevention Study) and, taking into account an uncertainty factor of 5, has proposed a provisional UL of 4 mg/day for the supplementation of β-carotene (VKM, 2015).

The D-A-CH Societies[3] provide a range of estimated values for a desirable intake of β-carotene between 2 and 4 mg/day (D-A-CH, 2015; Table 2).

**Table 2: Dietary reference values (estimated values) and UL**

| Age groups | Estimated values for a desirable intake | UL** |
|---|---|---|
| | mg/day | |
| Children and adults of all age groups | 2–4* | 15 |

* 1 mg Retinol equivalents (RE) = 1 mg retinol = 6 mg all-trans-β-carotene (EFSA, 2015), d.h. 2–4 mg β-carotene = 0.33–0.66 mg RE

[2] This would ascertain that the exposure to β-carotene from these uses would remain below 15 mg/day, the level of supplemental intake of β-carotene for which epidemiological studies did not reveal any increased cancer risk (EFSA, 2012a).

[3] German-Austrian-Swiss Nutrition Societies

1 mg Retinol activity equivalents (RAE) = 1 mg retinol = 12 mg β-carotene (D-A-CH, 2020), d.h. 2–4 mg β-carotene = 0.17–0.33 mg RAE

** The additional daily intake of β-carotene as a food supplement and food colouring considered as not giving rise to concerns by EFSA is not a UL in the strict sense

## 2.2 Exposure

According to the second National Food Consumption Survey (NFCS II), median β-carotene intakes in the age group 14 to 18 years was between 3.8 mg (m) and 3.9 mg (f) and 10.7 mg (m) and 11.1 mg (f) per day at the 95th percentile. Males and females over 18 years of age had median intakes between 3.9 and 4.4 mg/day and between 3.9 and 4.7 mg/day, respectively, and the 95th intake percentiles were between 10.0 and 13.0 mg/day and between 11.2 and 13.4 mg/day, respectively (MRI, 2008).

According to the data of the EsKiMo study (nutrition module in KiGGS[4]), the median β-carotene intake in children aged six to eleven years was between 1.7 and 2.3 mg/day (boys) and between 2.0 and 2.1 mg/day (girls) and the 95th intake percentiles were between 6.8 and 8.7 mg/day (boys) and between 5.5 and 9.9 mg/day (girls). At twelve to 14 years of age, the median intake was 3.3 to 3.5 mg/day for boys and 4.1 to 4.4 mg/day for girls; the 95th percentiles for boys and girls in this age group ranged from 12.2 to 12.7 mg and from 11.1 to 14.6 mg per day, respectively (Mensink et al., 2007).

The median β-carotene intakes achieved through the usual diet in Germany are thus within the range of estimated desirable intakes derived by the D-A-CH Societies in all age groups of children from six years upwards and adults.

## 2.3 Aspects considered in the derivation of maximum levels for β-carotene

- A market research conducted by the BfR in 2013 in supermarkets in Berlin as well as on the internet revealed that currently, in addition to food supplements, especially fruit juices, soft drinks and table drinks, breakfast cereals, cocoa and chocolate drinks as well as other dairy products contain β-carotene additions for nutritional purposes (Gerber, 2014).

- Taking into account the established fortification practice in Germany of conventional foods, in particular regarding fortification of juices and soft drinks with β-carotene, there is a risk that part of the population exceeds the supplementary intake level of 15 mg/day, which according to EFSA does not give rise to concerns about adverse health effects in the general population (Gerber, 2014).

- A re-evaluation of the NFCS II data by the MRI on the intake of (multiple) food supplements showed that about 16 % of the food supplement users identified in the NFCS II took a vitamin A preparation, whereby no differentiation between products with preformed vitamin A and β-carotene was possible on the basis of the data collected. Just under 3% of vitamin A supplement users took more than one food supplement; 2.4% (3.3% of men and 1.9% of women) of them took two products and 0.2% took three products (Römer and Heuer, 2017).

  It must be taken into account that the information on the supplements used by the NFCS II

[4] German Health Interview and Examination Survey for Children and Adolescents

participants as well as the nutrient data from the MRI supplement database are taken from the years 2005 to 2007. A change in the intake behaviour of the population and the nutrient composition of the supplements over the last ten years cannot be ruled out (Römer and Heuer, 2017).

### *2.3.1 Possible risk groups for high β-carotene intakes*

- According to a survey on the smoking status of adult men and women in Germany (GEDA study 2009), 30 % of those aged 18 and over (26 % of women and 34 % of men) smoke, with 24 % of them smoking daily and 6 % occasionally. Another 26% of adults have quit smoking; 44% reported never having smoked. This means that the number of adults who smoke or have ever smoked in Germany amounts to about 20 and 38 million, respectively. The proportion of heavy smokers (more than 20 cigarettes per day) was 5% of women and 9% of men in 2009 (Lampert, 2011).

- Since the mechanisms underlying the negative effects discussed in relation to β-carotene supplementation have not yet been clarified, it cannot be ruled out that there is also an increased risk of negative effects from high intakes of isolated β-carotene in individuals exposed to high concentrations of airborne toxic substances other than tobacco and asbestos. There is also an ongoing discussion about a theoretically increased risk in individuals with chronic lung diseases [e.g. asthma (8-10 % of adults[5]) or chronic obstructive pulmonary disease (10-12 % of adults > 40 years[3])], who could possibly react with an increase in symptoms after supplementation of β-carotene (VKM, 2015; BfR Commission, 2015[6]).

### *2.3.2 Derivation of maximum levels for β-carotene*

The following derivation of maximum levels - in the absence of a UL – is based on the daily intake value of below 15 mg proposed by EFSA (2012 a and b) for supplemental intake of β-carotene. As this value refers to *supplemental* intake only, in the view of the BfR, the addition of β-carotene for nutritional purposes to conventional foods must also be taken into account in addition to the use of β-carotene as a food colourant and the exposure to food supplements containing β-carotene. The β-carotene intake via the usual diet, on the other hand, can be disregarded in the derivation of maximum levels.

The residual amount available for food supplements and fortification of conventional foods is the difference between 15 mg/day (EFSA value) and the estimated average β-carotene intake from use as food colourat (1.5 mg/day):

Residual amount = 15 mg/day - 1.5 mg/day = 13.5 mg/day.

If the residual amount is divided equally between food supplements and other foodstuffs, a residual amount of 6.75 mg/day is available for addition to food supplements and conventional foodstuffs.

[5] https://www.lungeninformationsdienst.de/krankheiten/copd/index.html

[6] 7th Meeting of the BfR Commission on Nutrition, Dietetic Products, Novel Foods and Allergies, Minutes of the Meeting of 11 June 2015 (http://www.bfr.bund.de/cm/343/7-sitzung-der-bfr-kommission-fuer-ernaehrung-diaetische-produkte-neuartige-lebensmittel-und-allergien.pdf; German only)

## 2.4 Maximum levels for β-carotene in food supplements

If the residual amount of 6.75 mg/day is taken as a basis and an uncertainty factor of 2 is applied for use of multiple β-carotene-containing food supplements (which cannot be excluded), among other scientific uncertainties, this results in a maximum amount of 3.5 mg β-carotene per daily recommended dose of a food supplement. According to the applicable conversion factors (6 mg β-carotene = 1 mg RE = 0.5 mg RAE), this level corresponds to 0.6 mg RE or 0.3 mg RAE, respectively. Consequently, also with respect to dietary reference values for vitamin A (D-A-CH, 2020; EFSA, 2015), significant intakes of RE can be achieved by adding β-carotene to food supplements at this level.

## 2.5 Maximum levels for β-carotene in fortified conventional foods

If the residual amount$_{FF}$ of 6.75 mg/day available for fortified foods is allocated to the estimated daily energy intake from fortified foods, i.e., 15 to 30% of the daily energy intake, depending on the desired level of protection, the maximum tolerable β-carotene levels range from 0.5 to 2.3 mg/100 kcal, depending on age (Table 3).

In order to ensure that the intake of β-carotene from fortified foods and food supplements does not cause any of the age groups to exceed the residual amount of 13.5 mg/day, the lowest of the β-carotene levels resulting from the calculations is proposed as maximum level for the entire population: Assuming that the fortified food market is 'saturated', i.e. 30% of the daily energy is consumed in the form of fortified foods, this is 0.5 mg/100 kcal, and assuming that only a smaller proportion of fortifiable foods are actually fortified and consumed in fortified form (15% of energy intake from fortified foods), this is 1.0 mg/100 kcal (Table 3).

**Table 3: Daily energy intake (P95) and β-carotene levels assuming that 15% or 30% of the energy intake comes from fortified foods**

| Age groups | Energy intake (P95) | Fortification of 15 % of daily energy intake | | Fortification of 30 % of daily energy intake | |
|---|---|---|---|---|---|
| | | 15 % of energy intake | β-carotene* | 30 % of energy intake | β-carotene* |
| | *kcal/day* | *kcal* | *mg/100 kcal* | *kcal* | *mg/100 kcal* |
| 4 to 6 years | 2,000 | 300 | 2.3 | 600 | 1.1 |
| 7 to 9 years | 2,400 | 360 | 1.9 | 720 | 0.9 |
| 10 to 11 years | 2,550 | 383 | 1.8 | 765 | 0.9 |
| 12 years | 3,900 | 585 | 1.2 | 1,170 | 0.6 |
| 13 to < 15 years | 3,900 | 585 | 1.2 | 1,170 | 0.6 |
| 15 to < 17 years | 4,000 | 600 | 1.0 | 1,200 | 0.5 |
| Adults | 3,500 | 525 | 1.3 | 1,050 | 0.6 |

* the residual amount$_{FF}$ of 6.75 mg/day is allocated to 100 kcal portions

*2.5.1 Conversion of energy-based maximum levels into maximum amounts per 100 g of solid foods and per 100 ml of beverages*

The conversion of the energy-based maximum levels into maximum amounts per 100 g of solid foods was carried out by use of data from Schusdziarra et al. (2010) and Bechthold (2014), who, for normal-weight adults and for the entire NFCS II population, respectively, determined an average energy density for solid food consumed of about 170 kcal/100 g. Since it is difficult to estimate which food (groups) will actually be fortified (in the future), also in view of alternative fortification practices, it seems appropriate from the BfR's point of view to use the average energy density of 170 kcal/100 g determined by Schusdziarra et al. (2010) and Bechthold (2014) for the derivation of maximum levels for solid foods.

The consumption of energy-containing beverages was not considered by Schusdziarra et al. (2010) and Bechthold (2014). However, since it is known that juices and soft drinks in Germany are very often fortified with micronutrients, an average energy density of about 45 kcal/100 ml was determined for this product group by the BfR on the basis of the information contained in the German Food Code and Nutrient Database (BLS) 3.01.

Energy-containing beverages and solid foods are considered separately below. Taking into account the respective average energy densities, weight-based maximum levels for β-carotene are provided in the following table (Table 4).

**Table 4: Conversion of energy-based to weight-based maximum levels**

| **β-carotene per 100 kcal** | **Solid foods** (energy density: 170 kcal/100 g) | **Drinks** (energy density: 45 kcal/100 ml) |
|---|---|---|
| 0.5 mg | 0.85 mg (0.14 mg RE)/100 g | 0.23 mg (0.04 mg RE)/100 ml |
| 1 mg | 1.7 mg (0.28 mg RE)/100 g | 0.45 mg (0.08 mg RE)/100 ml |

If one considers as an additional criterion that the added amounts of β-carotene should be significant in order to be allowed to be claimed in the labelling of the product according to the current legal situation, then according to Regulation (EU) No. 1169/2011 at least 15 % of the reference value for nutrition labelling must be contained in a product per 100 g or at least 7.5% per 100 ml in the case of beverages.
In Regulation (EU) No 1169/2011, the reference value for vitamin A is 800 µg. Taking into account the conversion factor for RE of 1 mg RE = 6 mg β-carotene, this corresponds to 4.8 mg β-carotene. Accordingly, solid foods would have to contain at least 0.72 mg/100 g and beverages at least 0.36 mg/100 mL of β-carotene. The β-carotene content of 0.23 mg/100 mL calculated in Table 4 for the saturated market of fortified foods would therefore not be considered a significant amount.

In such cases, it is proposed to exempt further food (categories) from fortification, in addition to those mentioned in Article 4 of Regulation (EC) 1925/2006.

Thus, the addition of β-carotene for nutritional purposes could be limited to the three food groups currently most commonly fortified with β-carotene, namely "breakfast cereals", "dairy products" and "juices and soft drinks", and the lowest amount of β-carotene, classified as significant according to Regulation (EU) No 1169/2011, of 0.72 mg/100 g for solid foods and of

0.36 mg/100 ml for liquid foods, could be set as the maximum level. The results of model calculations carried out in 2014 on the basis of NFCS II data *(Diet History data)*[7], suggest that if β-carotene be used at those levels to fortify foodstuffs, the acceptable intake of 15 mg/day proposed by EFSA would not be exceeded by the adult population.

Alternatively, juices and soft drinks, whose consumption is difficult to limit and may therefore lead to exceptionally high intakes of β-carotene in high consumers, could be exempted from fortification with β-carotene, thus limiting the addition of β-carotene for nutritional purposes to solid foods.

**Further information on the BfR website on the subject of vitamins**

A-Z Index on vitamins: https://www.bfr.bund.de/en/a-z_index/vitamins-130216.html

Topic page on the assessment of vitamins and minerals in foods: https://www.bfr.bund.de/en/vitamins_and_minerals-54417.html

"Opinions app" of the BfR

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[7] In the model calculations carried out, a scenario was calculated in which the fortification of the three food groups most commonly fortified in Germany, "breakfast cereals", "dairy products" and "juices and soft drinks", was simulated with 0.72 mg β-carotene per 100 g or 100 ml of each of the three food groups, and it was also assumed that consumers would consume exclusively fortified foods of these food groups (*worst case scenario*).

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**About the BfR**

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the German federal government and German federal states ("Laender") on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

*This text version is a translation of the original German text which is the only legally binding version.*