

Annex to: EFSA NDA Panel, 2024. Scientific opinion on the Tolerable Upper Intake Level for preformed vitamin A and β -carotene. doi:10.2903/j.efsa.2024.8814

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Annex B - Methodological considerations in the calculation of intake estimates for preformed vitamin A and β -carotene from the background diet in EU countries

1. Introduction

The intake assessment follows the approach outlined in the protocol for the intake assessments performed in the context of the revision of ULs for selected nutrients (EFSA, 2022a), and focuses on the intake of preformed vitamin A and β -carotene derived from their natural content in foods and the use of β -carotene as food additive as consumed by EU populations.

The food composition and consumption data used for the intake assessment were classified according to the ‘exposure hierarchy’ of the FoodEx2 classification and description system to facilitate the linkage between occurrence/composition data and food consumption data (EFSA, 2015).

FoodEx2 includes a list of more than 4,500 entries, referred to as ‘FoodEx2 base terms’. These were aggregated into food groups and broader food categories in a hierarchical parent-child relationship (up to 7 levels), from the most generic (e.g., level 1, grain and grain-based products) to the most specific level (e.g., level 7, cream cheesecake). In addition, a catalogue of 28 ‘facets’ is available to describe further characteristics of the foods, such as physical state (e.g., powder, liquid, etc.) or processing technology (e.g., grinding, milling, crushing, etc.). Details on the FoodEx2 classification system are available in the dedicated page of the EFSA website¹.

2. Sources of food composition data

2.1. The EFSA Food Composition Database

Composition data for preformed vitamin A and β -carotene in foods and beverages were derived from the EFSA Food Composition Database (FCDB), which was compiled as a deliverable of the procurement project “Updated food composition database for nutrient intake” (Roe et al., 2013). The project provided EFSA with an updated food composition database covering approximately 1,750 food entries and additional facet descriptors included in the EFSA classification system (FoodEx2, see Section 1.1), and delivered harmonised information on the most common composite recipes across European countries up to 2012. The data are sourced from scientific literature, analytical results, imputation based on other foods considered to have analogous content, and calculations from recipes. In case no country-specific data were available for certain food codes, data compilers borrowed compatible data from other countries and/or from similar foods. The EFSA FCDB contains data for energy, macro-, and micronutrients from national food composition databases up to 2012, provided by 14 national food database compiler organisations. Data on preformed vitamin A (indicated as “retinol” only) and β -carotene were provided by 11 countries.

2.2. Publicly available food composition databases

For gap-filling and cross-checking the quality of the available data, additional publicly available national databases from the following countries were consulted:

¹ <http://www.efsa.europa.eu/en/data/data-standardisation>

For preformed vitamin A: Denmark (Frida, 2022), Estonia (NutriData, 2022), France (Anses, 2020), Netherlands (NEVO, 2021), Norway (Norwegian Food Safety Authority, 2022) and Sweden (The Swedish Food Agency, 2022).

For β -carotene: Denmark (Frida, 2022), Estonia (NutriData, 2022), Finland (Fineli, 2019), France (Anses, 2020), Netherlands (NEVO, 2021), Portugal (PortFIR, 2021), Sweden (The Swedish Food Agency, 2022), Italy (Marletta and Camilli, 2019).

Regarding the selection of the food composition databases to be considered, decisions were made based on the availability of composition levels in the publicly available databases and the aim to provide a representative geographical coverage complementing the countries in the EFSA FCDB. In addition, preference was given to more recent composition values when multiple options were available.

2.3. The Mintel’s Global New Products Database

The Mintel’s Global New Products Database (GNPD) was used to check and complement the data on the vitamin A content of foods and beverages according to the nutrition information on the packaging label and the ingredients list². Mintel GNPD is an online database that monitors new introductions of packaged goods in the global market. It contains information on over 3 million food and beverage products, with more than 1,100,000 being currently or previously available in the European food market. Mintel began covering European food markets in 1996, currently having 25 out of 27 EU Member States, the UK, and Norway represented.

The database was accessed in 2023 to facilitate the development and cleaning of the EFSA FCDB.

3. Data cleaning and validation of the EFSA Food Composition Database

3.1. Data cleaning

During the cleaning procedure, the consistency of FoodEx2 codes, the original food name in English (freely entered text) and the composition values of respective food items were scrutinised, particularly for records with outlier values. The process involved checking the range of minimum and maximum values per food category at the most specific FoodEx2 level. If a 10-fold or higher difference was observed, the raw data were investigated further. The variability in content was evaluated for each FoodEx2 code, considering that, in certain cases, the observed 10-fold difference was justified by inherent product or commodity variability. Where confirmation of the product variability was needed or insufficient data were available, Mintel GNPD and/or other publicly available food composition tables were consulted. Outliers were deleted if confirmation of the relatively high or low values could not be obtained from Mintel GNPD or freely available composition tables.

As the scope of intake assessment was to consider only natural food sources, data on food supplements were disregarded, and an attempt was made to exclude fortified foods from the composition database, including foods for weight reduction³, and single meal replacements⁴. For fortified foods, the free text description of the product, the brand name and the facet information were inspected to identify them. Additionally, high outlier values were cross-checked as they could refer to fortified foods.

A specific approach was required for checking fortified foods for β -carotene, given its use as a food additive (food colour under the number E 160a) in various composite food products such as pastries, biscuits, confectionary or fruit soft drinks. β -carotene content in foods where it is used as food colour

² <https://www.mintel.com/global-new-products-database>

³ Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction

⁴ Commission Delegated Regulation (EU) 2017/1522 of 2 June 2017 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for total diet replacement for weight control

cannot be distinguished analytically from its content as fortifying agent. Thus, β -carotene content in certain composite foods reported in composition databases may include both. This assessment aimed to include the intake of β -carotene used as food additive but exclude its use for fortification purposes but this was not always possible. Consequently, a more inclusive approach was adopted, potentially leading to the inclusion of some unidentified fortified foods.

In addition, both for preformed vitamin A and β -carotene, some food items with inaccurate FoodEx2 classification (e.g., prepared porridge coded as dry raw material, milk-based dessert coded as water-based dessert) were recoded.

The following entries in the EFSA FCDB were disregarded:

- FoodEx2 codes no longer in use (dismissed/deprecated terms);
- FoodEx2 codes not corresponding with free text description (incorrect coding);
- FoodEx2 codes with no reported eating occasions in the EFSA Comprehensive Food Consumption Database.
- FoodEx2 codes referring to cooked foods, as most eating occasions in the EFSA Comprehensive European Food Consumption Database (section 3) refer to the raw quantities. Retention factors (RFs) were applied to raw foods (for more information see section 4 and Annex C, Table 3 for preformed vitamin A and Annex D, Table 3 for β -carotene).

For preformed vitamin A, major food categories like fruits, vegetables and products thereof were not relevant for the intake assessment, as they do not contain retinol. For other food categories, the last step of data cleaning was to assume a preformed vitamin A concentration of 0 $\mu\text{g}/100\text{g}$ for specific food items/subcategories not expected to contain retinol.

After removing duplicates (borrowed values, Section 2.1.1.) and implementing the cleaning procedure described above, the EFSA FCDB contained a total of 2,569 unique records for preformed vitamin A and 3,794 for β -carotene. These records corresponded to 274 and 1,282 distinct FoodEx2 base terms, respectively (Table 1).

Table 1. Number of unique entries in the EFSA FCDB for preformed vitamin A and β -carotene by country.

Country	Preformed vitamin A	β -carotene
Germany	881	1149
Denmark	162	419
Finland	283	487
France	315	531
United Kingdom	251	194
Greece	99	39
Iceland	45	106
Italy	37	-
Netherlands	249	532
Portugal	132	-
Serbia	-	7
Sweden	115	271
Slovenia	-	59
Grand Total	2569	3794

3.2. Gap filling procedure for preformed vitamin A

The following steps were followed to fill data gaps for preformed vitamin A in the cleaned EFSA FCDB (Annex C, Table 1):

- a) Values for FoodEx2 codes were extrapolated to categories for which the concentration of preformed vitamin A was expected to be similar (e.g. values of bovine meat to bovine meat, minced);
- b) For food categories that are relevant dietary sources of preformed vitamin A (e.g. offal, meat products, eggs) and for which composition values were provided by less than three countries, the database was completed by adding composition values from other publicly available composition tables (Section 2.1.2) and Mintel GNPD (Section 2.1.3);
- c) The average content of preformed vitamin A in FoodEx2 base terms was propagated to their less specific FoodEx2 levels (i.e. parent categories) and used to calculate average concentration values for these FoodEx2 codes;
- d) For FoodEx2 codes for which the propagation exercise did not provide a realistic estimate, ad-hoc assumptions were exceptionally made.

After the gap filling exercise, composition values for a total of 327 FoodEx2 categories were available in the final EFSA FCDB to estimate preformed vitamin A intakes (Annex C, Table 2). For each FoodEx2 category, an average preformed vitamin A concentration value was obtained by pooling the data from different countries.

3.3. Gap-filling procedure for β -carotene

The following steps were followed to fill data gaps for β -carotene in the cleaned EFSA FCDB (Annex D, Table 1):

- a) For food categories that are relevant dietary sources of β -carotene and for which composition values were provided by less than three countries, the database was completed by adding composition values from other publicly available composition tables (Section 2.1.2) and Mintel GNPD (Section 2.1.3).
- b) FoodEx2 base terms were propagated to lower and higher levels. For example, values on a less specific (parent) level ('Grapes and similar fruits') were propagated to its 'children' levels ('Table grapes', 'Wine grapes', 'Muscadine grapes'), while for less specified food categories of the 'parent' code (e.g. 'Fruit / vegetable spreads and similar'), the mean of the values of all its 'children' codes was assigned.
- c) All food categories, and especially relevant dietary sources of β -carotene, were checked manually. When the automatic propagation did not result in realistic estimates for some categories, the gap filling was performed by borrowing values from a similar category (e.g. the mean value from 'Cocoa powder' was inherited by the food category: "Cocoa beverage-preparation, powder") or was calculated by application of a (reverse) dilution factor: e.g. composition levels for fruit juice concentrates (e.g. orange, grape, blackberry) were estimated from the β -carotene content of juices assuming a factor of 5, which was calculated from the ratio of 'Fruit juices (100% from named source)' and 'Fruit juice concentrates'. This second level of gap filling, together with the propagation, is documented in Annex D, Table 2.

After the gap filling exercise, a total of 1757 FoodEx2 categories were selected, were available in the final EFSA FCDB to estimate β -carotene intakes (Annex D, Table 2). For each FoodEx2 category, an average β -carotene concentration value was obtained by pooling the data from different countries.

4. EFSA Comprehensive European Food Consumption Database

The EFSA Comprehensive European Food Consumption Database (hereafter referred to as Comprehensive Database) provides a compilation of existing national information on food consumption at individual level and was first built in 2010 (EFSA, 2011b, a; Huybrechts et al., 2011). Details on how the Comprehensive Database is used are published in the Guidance of EFSA (EFSA, 2011b). The latest version of the Comprehensive Database, updated in 2022, contains results from a total of 83 different dietary surveys carried out in 29 different European countries (including EU Member States, pre-accession countries and the UK) covering 154,388 individuals.

For long-term dietary intake assessment, food consumption data were available from 49 different dietary surveys carried out in 22 different European countries. Dietary surveys with only one day per subject were excluded from the current assessment because they were deemed to be inadequate to assess habitual intake. In most cases, when for one country and age class different dietary surveys were available, only the most recent was used. However, when two national surveys from the same country gave a better coverage of the age ranges of the standard population groups, both surveys were kept (e.g. two surveys in young adolescents in Estonia). Nine surveys provided information on specific population groups, six on pregnant women (15 to 49 years old), two on lactating women (18 to 45 years old) and one on vegetarians (12 to 70 years old). Details on the characteristics of these surveys (i.e., name, population group covered, number of subjects, number of consumption days recorded, and dietary method used) can be found in Annex C, Table 4 (for preformed vitamin A) and Annex D, Table 4 (for β -carotene).

Consumption data were collected using repeated 24-hour dietary recalls or dietary records covering from two to nine days per subject. Due to differences in the methods used for data collection, direct country-to-country comparisons should be interpreted with caution.

For the present intake assessment, subjects were reclassified in different age categories (population groups) as follows:

Infants:	≥ 4 to < 12 months old
Toddlers:	≥ 12 months to < 36 months old
Young children:	≥ 36 months to < 7 years old
Older children:	≥ 7 years to < 10 years old
Young adolescents:	≥ 10 years to < 14 years old
Older adolescents:	≥ 14 years to < 18 years old
Adults:	≥ 18 years to < 65 years old
Older adults:	≥ 65 years old

For the purpose of this opinion infants below 4 months were excluded from the assessment as it is assumed that they are exclusively breastfed or fed with breast milk substitutes (EFSA, 2018); additionally, the age categories ‘other children’ and ‘adolescents’ were split into two subgroups.

Individuals aged 65 years and older will be referred to as older adults in this document, which encompasses the age categories ‘elderly’ and ‘very elderly’ described in the EFSA Comprehensive database (EFSA, 2011b) and defined in the protocol.

In this opinion, food consumption data provided by non-EU Countries, i.e. pre-accession countries and the UK were not taken into consideration as the assessment of intake for these countries is outside the scope of this mandate.

5. Database on retention factors

Since preformed vitamin A and β -carotene are sensitive to the heat treatment of the foods, to be able to properly consider the cooking processes, a database of retention factors was extracted from the report published by the European Food Information Resource (EuroFIR) in 2008 (Vásquez-Caicedo et al., 2008), namely 'Report on collection of rules on use of recipe calculation procedures including the use of yield and retention factors for imputing nutrient values for composite food'⁵. Food categories and cooking methods from the report were matched with the corresponding FoodEx2 codes and cooking-related facets (see more information in Section 2). In Annex C, Table 3 (for preformed vitamin A) and Annex D, Table 3 (for β -carotene), a list of the extracted retention factors matched with the corresponding FoodEx2 base terms and cooking related facet are presented.

While matching retention factors derived from the EuroFIR report to the Comprehensive database, the following principles were followed:

- for composite dishes (e.g., cooked pasta, meat-based dishes, soups) or ready to eat processed foods (e.g., fine bakery wares, bread) no retention factors were applied since the values in the composition table were already corresponding to the prepared form, and their reported quantities in the Comprehensive Database are expressed "as consumed".
- for bread, rolls, and fine bakery wares, which in the vast majority of the food consumption surveys are not disaggregated into their ingredients, preformed vitamin A/ β -carotene levels were matched directly to the content in the final product.
- for foods that are not supposed to be eaten raw or are not frequently eaten raw, a retention factor was assumed and applied even if no cooking related facet was indicated. This approach was taken for cereal grains (excluding breakfast cereals), groats and semolina, unprocessed eggs, flowering brassica, brussels sprouts, fresh meat, fish meat, offal, seafood, legumes and pulses, potato, and starchy roots, as well as raw doughs and pasta. In the cases when for example a vegetable can be consumed both raw and cooked (e.g., cabbage, carrot) retention factors were assigned only when a cooking related facet was reported.
- when more than one cooking related facet (e.g., baked and boiled) was assigned to the food of an individual eating occasion in the Comprehensive Database, the cooking method with the lowest retention factor assigned was kept.
- Fish and fish products (relevant for preformed vitamin A): separate RFs were available for fat or lean fishes. In the distinction of fat and lean fishes a cut off of 2% fat content on a fresh basis was assumed, as per FAO/WHO definition⁶. Most conservative RF (lean fish) was applied whenever information on the fat content of specific fishes could not found, or the FoodEx2 category included both lean and fat fishes.

6. Intake assessment methodology

Dietary intakes of preformed vitamin A and β -carotene were calculated (in $\mu\text{g}/\text{day}$ and mg/day , respectively) by linking food consumption data at individual level in the Comprehensive Database to food composition data at the relevant FoodEx2 level. For each dietary survey, the average daily consumption of each food item was combined with its content of preformed vitamin A/ β -carotene. The resulting intakes per food item were summed up in order to obtain daily intakes for each individual. The mean, P5, Median and P95 of intakes were calculated for each survey by population group and sex, as well as total populations (without distinction of sexes). Intake results for preformed vitamin A are

⁵ <https://www.eurofir.org/wp-content/uploads/2014/05/6.-Report-on-collection-of-rules-on-use-of-recipe-calculation-procedures-including-the-use-of-yield-and-retention-factors-for-imputing-nutrient-values-for-composite-foods..pdf>

⁶ FAO/WHO, 2020. Code of Practice for Fish and Fishery Products. Rome, Italy. 372 pp.

provided in Annex C (Tables 5 and 6), and for β -carotene in Annex D (Tables 5 and 6). The contribution of different foods, subcategories, and major parent categories (Level1) to mean intake of preformed vitamin A/ β -carotene by country, survey and population classes are available for preformed vitamin A in Annex C (Tables 7, 8) and 9 and for β -carotene in Annex D (Tables 7, 8) and 9.

Intake scenarios for preformed vitamin A

The standard intake assessment (i.e., using data as reported in food consumption surveys) led to very high 95th percentile (P95) intake values across surveys for all population groups, except vegetarians. The top contributing food to preformed vitamin A intake was offal (including liver and other edible offal and offal-based processed products), which accounted for up to 72% of the intake in adults and up to 76% in older adults. Food consumption surveys recording only two or three days (i.e., 46 out of the 53 food consumption surveys present in the EFSA Comprehensive database) cannot accurately capture the habitual intake of foods consumed with a lower frequency, as is typically the case of offal and products thereof. When offal consumption is reported in one or more of the 2-3 survey days, intakes can be overestimated if offal is actually consumed less frequently than on a weekly basis. Conversely, if offal is consumed but not captured in the 2-3 survey days, actual intakes will be underestimated. Whereas these two errors are expected to compensate for each other in large samples regarding mean intakes, substantial errors at both the low and high percentiles of intake are expected.

To obtain a more realistic picture on the P95 intake of preformed vitamin A for the whole population, the frequency of offal consumption in offal consumers was adjusted to once per month, twice per month, and once per week to build specific intake scenarios using the portion sizes for each individual as reported in the EFSA Comprehensive Database.

A fictive example is presented in Table 2 on how the specific intake assessment scenarios are calculated for Participant A in a 2-day dietary survey. In this example, Participant A consumed pig liver in both survey days and liver sausage in one survey day. The originally reported quantities for offal were divided by 31, 15 and 7 to construct the scenarios once per month, twice per month, and once per week respectively (Step1). The amounts consumed in day 1 and day 2 were then summed up for each food under each scenario (Step2). Consumption amounts of other types of foods (i.e. butter biscuits and boiled eggs in this example) were not changed for any of the scenarios. The consumed quantities were linked to the composition levels and intake of preformed vitamin A was calculated for each food under each consumption scenario (Step3). Intakes were then summed up by participant (Step4).

After applying this procedure for each participant, the P95 values per population group, country and survey can be derived for each consumption scenario.

Table 2. Example of calculations for scenarios with adjustments for offal consumption with fictive data

Consumed Food	Consumption day from the total 2 days	Consumption as reported (g)	Consumption Standard scenario (g)	Consumption amount considered (g) in the offal consumption scenarios		
				Offal 1x /month	Offal 2x /month	Offal 1x /week
Pig liver	1	100	50	3.2	6.7	14.3
Liver sausage	1	50	25	1.6	3.3	7.1
Butter biscuits	1	70	35	35	35	35
Pig liver	2	50	25	1.6	3.3	7.1
Boiled eggs	2	25	12.5	12.5	12.5	12.5

Step2: Total consumption by food for Participant A and composition levels of the consumed foods

Consumed Food	Composition ($\mu\text{g}/100\text{g}$)	Consumption as reported (g)	Consumption Standard scenario (g)	Consumption amount considered (g) in the offal consumption scenarios		
				Offal 1x /month	Offal 2x /month	Offal 1x /week
Pig liver	19925	150	75	4.8	10.0	21.4
Liver sausage	5545	50	25	1.6	3.3	7.1
Butter biscuits	131	70	35	35	35	35
Boiled eggs	213	25	12.5	12.5	12.5	12.5

Step3: Intake by food ($\mu\text{g}/\text{day}$) for Participant A in the different offal consumption scenarios

Consumed Food	Standard scenario	Offal 1x /month	Offal 2x /month	Offal 1x /week
Pig liver	14943	964	1992	4270
Liver sausage	1386	89	185	396
Butter biscuits	92	92	92	92
Boiled eggs	53	53	53	53

Step4: Total Intake ($\mu\text{g}/\text{day}$) for Participant A in the different offal consumption scenarios

	Standard scenario	Offal 1x /month	Offal 2x /month	Offal 1x /week
Total intake	16474	1198	2322	4811

Preformed vitamin A intake estimates for the adjusted offal consumption scenarios are presented in Annex C (Tables 5 and 6) together with the results of the ‘standard’ scenario. Information on contributing foods, food categories and major parent categories (Level 1) for the intakes excluding offal can be found in Annex C (Tables 10, 11, 12).

In addition, preformed vitamin A intake of offal consumers only was also estimated. The number and percentage of offal consumers by survey, and intake results by population group, country and survey are presented in Annex C (Table 6). Information on contributing foods, food categories and major parent categories (Level 1) for offal consumers only can be found in Annex C (Tables 13, 14, 15).

All analyses were conducted using the SAS Statistical Software (SAS enterprise guide 8.3).

Intake data from national estimates

According to the intake assessment protocol (EFSA, 2022), the accuracy of the results obtained should be evaluated by comparing EFSA’s estimates with published national background intake estimates. These comparisons exclude food supplements and fortified foods, and are made with the same surveys, similar data collection windows, and population groups, when available ([Section 2.2.1](#)).

Presently, only Belgium has published intake estimates for preformed vitamin A that correspond to the same surveys and population groups as in EFSA’s Comprehensive database. However, the use of two 24-h recalls in combination with dietary assessment methods (FFQ or dietary interview) to adjust for the frequency of food consumption, which is relevant to rarely consumed foods such as liver, offal and products thereof, invalidates comparisons with EFSA’s standard intake estimates for that survey (two 24-h recalls only).

For β -carotene, for the purpose of this comparison, only estimates from national surveys in Austria, and Estonia could be used. In these surveys, mean and P95 intakes were in line with the estimates calculated by EFSA for most population groups.

6.1. Sources of uncertainty

Consumption data

Uncertainties and limitations arising from the use of the EFSA Comprehensive Food Consumption Database have been described in detail elsewhere (EFSA, 2011a), and relate to the following methodological aspects:

- Sampling strategy and response rate: using sampling strategies that are convenient (e.g. use of household as sampling unit rather than individuals, target recruitment through universities, pharmacies or factories vs. using national population registers) and low response rates may lead to survey samples which are not representative of the general population at national level. This could lead to over- or underestimation of the intakes in the general population at national level.
- Representativeness over different weekdays and seasons: surveys not covering both weekdays and weekend days, or conducted on one season only, may not capture habitual intakes mostly for foods which are consumed seasonally only or on special occasions (e.g. weekends). However, most surveys in the Comprehensive Database, especially the vast majority of those conducted under the EU-Menu project (EFSA, 2014), cover a whole year period with an appropriate proportion of weekdays and weekend days.
- Methodology used to assess dietary intakes: dietary recall (e.g. retrospective method, the memory of the participant can affect the results) vs. food records (e.g. if self-reported, portion size estimation can be difficult to the subject, reporting errors can occur) (see Annex C, Table 3 and Annex D, Table 3).
- Use of standard portion sizes: this can lead to over- or underestimation of the actual quantity consumed.
- Inclusion of consumption surveys covering only a few days: this leads to overestimation of high percentiles of chronic intake, whereas it is expected to minimally affect mean intakes of nutrients widely distributed in the diet. For foods not consumed daily, P95 intakes could be over- or under-estimated depending on whether consumption days are captured in the survey.
- Other systematic errors: under-reporting has been shown to be associated with sex, age, educational level and body mass index (BMI) (e.g., subjects with obesity and male subjects underreport more frequently than subjects with BMI in the normal range and females).

Composition data

- The EFSA Food Composition Database contains data on preformed vitamin A/ β -carotene from national food composition databases up to 2012. If in the meantime, the national databases were updated or new foods were added to them, this is not reflected in the EFSA database. However, the procedures taken to clean the data, validate them, and fill the gaps likely minimise this uncertainty.
- For this opinion, food composition data from 11 and 12 European countries were pooled, considering a common EU food market, which may cover country-specific differences in the preformed vitamin A/ β -carotene concentration of different foods. However, this approach allowed for more food products to be considered per food category, leading to a more robust database which takes into account product variability. Most of the data in the EFSA Food Composition Database for both the preformed vitamin A and beta carotene assessment were coming from one country (Germany) which also adds some uncertainty as the EU market might not be accurately represented.

- Composition tables generally contain average values for a food, which may under- or over-estimate the actual preformed vitamin A/ β -carotene concentration of a certain food product consumed by one subject. However, it is expected that the uncertainty introduced by this factor is minimised when mean intakes are calculated for the population.
- As the scope of intake assessment was to consider natural sources of preformed vitamin A/ β -carotene only, a data cleaning strategy was applied to exclude fortified foods from the composition database. Since fortification was not always clearly reported, assumptions had to be made to exclude suspected fortified foods (e.g., by identifying outlier values).

Linkage of composition and consumption data

- Assumptions were made while assigning the preformed vitamin A/ β -carotene content of foods to the consumption occasions. Some consumption records were only coded on a very generic level (FoodEx2 Level 1 or Level 2), and it was not possible to identify the exact product consumed. In these cases, an average value at a lower FoodEx2 level was assigned to the record (e.g. if the eating occasion reported “Fine bakery wares” on FoodEx2 Level 2, the average of all “children” categories was assigned).
- The initial database of retention factors were coded in the Languag system, and were manually recoded in FoodEx2. Although an attempt was made to find the best possible match of the base terms and cooking facets, there might be slight differences between the definition of foods and processes between the two coding system.
- Composition, consumption, and retention factor database were matched through the selected relevant FoodEx2 level and through the reported cooking facet. When more than one cooking related facet was assigned to the food of an individual eating occasion in the Comprehensive Database, the cooking method with the lowest retention factor assigned was kept.
- Retention factors were also applied to foods that are assumed to be consumed cooked, even if no cooking related facet was applied. This might cause a slight underestimation in case these foods were actually eaten raw (e.g. meat actually consumed as ‘tartare’, raw salmon in sushi).

Intake assessment calculation

- Statistical models were not applied to calculate habitual intakes using the food consumption surveys available in the EFSA Comprehensive database. Whereas the observed individual means method accurately reflects mean intakes, it generally tends to provide conservative estimates of the higher percentiles of the intake distribution.

Uncertainties specific for the preformed vitamin A assessment

- Highest contribution of intakes are coming from the consumption of offal and offal products, which are typically known as less frequently consumed foods, for which the surveys recording only two or three days of food consumption cannot capture accurately the habitual intakes. When assessing the intake of a rarely consumed food with only few days of consumption, errors at both the low and high percentiles are expected.
- Feeding practices can influence the preformed vitamin A content in liver and other offal or offal based products. However, this uncertainty would be more relevant for products where brand-loyalty is typical for the consumers, otherwise the average values are most probably reflecting a realistic estimate since the offal consumed is purchased from different sources.
- Regarding the exact preformed vitamin A form in composition tables, including the EFSA FCDB, the term retinol is commonly used, although it includes also retinyl acetate and retinyl palmitate, alone or in combination. The EFSA FCDB does not provide content of retinyl esters in food.

Uncertainties specific for the β -carotene assessment

- β -carotene content of commodities and products depends on their colour. Especially for fruits and vegetables, in many cases it depends on the maturity or the colour variety (e.g. peaches with white or yellow flesh, green or white asparagus) of the commodities which parameters are not recorded in the composition tables, neither on the consumption database. It could cause both under- or overestimation in the individual intakes, however on population level the effect of this uncertainty is expected to be low.
- A specific approach was required for checking fortified foods for β -carotene, given its use as a food additive (food colour under the number E 160a) in various composite food products such as pastries, biscuits, confectionary or fruit soft drinks. β -carotene content in foods where it is used as food colour cannot be distinguished analytically from its content as fortifying agent. Thus, β -carotene content in certain composite foods reported in composition databases may include both. This assessment aimed to include the intake of β -carotene used as food additive but exclude its use for fortification purposes but this was not always possible. Consequently, a more inclusive approach was adopted, potentially leading to the inclusion of some unidentified fortified foods.
- When β -carotene content of certain more generic food categories is estimated the type of vegetable included in the food is unknown, e.g. 'Vegetable juices', 'Ready-to-eat meal for infants and young children' 'Dried vegetables'. Depending on their ingredients, e.g. if they contain carrot, the composition levels can vary in a very wide range. Thus, their contribution to the total intake can be both under- or overestimated.

Abbreviations and/or acronyms

BMI	Body Mass Index
EFSA	European Food Safety Authority
EU	European Union
EuroFIR	European Food Information Resource
FAO	Food and Agriculture Organization of the United Nations
FCDB	EFSA Food Composition Database
FFQ	Food Frequency Questionnaire
GNPD	Global New Products Database
RF	Retention Factor
UK	United Kingdom
UL	Tolerable Upper Intake Level
WHO	World Health Organization

References

- Anses, online. Table de composition nutritionnelle des aliments Ciqual. Version 2020. Available online: <https://ciqual.anses.fr/>
- EFSA, 2011a. Methodological characteristics of the national dietary surveys carried out in the European Union as included in the European Food Safety Authority (EFSA) Comprehensive European Food Consumption Database. Food Addit Contam Part A Chem Anal Control Expo Risk Assess, 28:975-995. doi: 10.1080/19440049.2011.576440
- EFSA (European Food Safety Authority), 2011b. Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. EFSA Journal 2011;9(3):2097. 34 pp. doi: 10.2903/j.efsa.2011.2097
- EFSA (European Food Safety Authority), 2014. Guidance on the EU Menu methodology. 1831-4732. 3944 pp. Available online: <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2014.3944>
- EFSA (European Food Safety Authority), 2015. The food classification and description system FoodEx 2 (revision 2). EFSA Supporting Publication 2015; 12(5):EN-804, 90 pp. doi: 10.2903/sp.efsa.2015.EN-804
- EFSA (European Food Safety Authority), 2018. Protocol for the scientific opinion on the Tolerable Upper Intake Level of dietary sugars. EFSA Journal 2018;16(8):5393, 47 pp. doi.org/10.2903/j.efsa.2018.5389
- EFSA (European Food Safety Authority), 2022a. Protocol for the intake assessments performed in the context of the revision of Tolerable Upper Intake Levels for selected nutrients. EFSA Supporting publication 2022:e200801. doi: 10.2903/sp.efsa.2022.e200801.
- EFSA, 2022b. Protocol for the intake assessments performed in the context of the revision of Tolerable Upper Intake Levels for selected nutrients. EFSA Supporting Publications, 19:E200801E. doi: 10.2903/sp.efsa.2022.e200801
- Fineli, online. Food Composition Database Release 20. Available online: <https://fineli.fi/fineli/en/index>
- Frida, online. Food data, version 4.2. Available online: <https://frida.fooddata.dk/>
- Huybrechts I, Sioen I, Boon PE, Ruprich J, Lafay L, Turrini A, Amiano P, Hirvonen T, De Neve M, Arcella D, Moschandreas J, Westerlund A, Ribas-Barba L, Hilbig A, Papoutsou S, Christensen T, Oltarzewski M, Virtanen S, Rehurkova I, Azpiri M, Sette S, Kersting M, Walkiewicz A, Serra-Majem L, Volatier J-L, Trolle E, Tornaritis M, Busk L, Kafatos A, Fabiansson S, De Henauw S and Van Klaveren JD, 2011. Dietary exposure assessments for children in europe (the EXPOCHI project): rationale, methods and design. Archives of Public Health, 69:4. doi: 10.1186/0778-7367-69-4
- Marletta and Camilli (Nutrizione CCAe), online. Tabelle di Composizione degli Alimenti. Available online: <https://crea.gov.it/-/tabella-di-composizione-degli-alimenti>
- NEVO, online. NEVO online version 2021/7.1. Available online: <https://nevo-online.rivm.nl/Home/En>
- Norwegian Food Safety Authority, online. Norwegian Food Composition Database, version 2022. Available online: <https://www.matvaretabellen.no/>
- NutriData, online. Food composition database, version 11. Available online: <https://tka.nutridata.ee/et/>
- PortFIR, online. Tabela da Composição de Alimentos versão 5.0-2021. Available online: <https://portfir-insa.min-saude.pt/>
- Roe MA, Bell S, Oseredczuk M, Christensen T, Westenbrink S, Pakkala H, Presser K and Finglas PM, 2013. Updated food composition database for nutrient intake. Project developed on the procurement project CFT/EFSA/DCM/2011/03. EFSA Supporting Publication 2013; 10(6):EN-355, 21 pp. doi:10.2903/sp.efsa.2013.EN-355
- The Swedish Food Agency, online. Food database, version 2002-05-24. Available online: <https://www7.slv.se/SokNaringsinnehall/>
- van Klaveren JD, Goedhart PW, Wapperom D and van der Voet H, 2012. A European tool for usual intake distribution estimation in relation to data collection by EFSA. EFSA Supporting Publications, 9:300E. doi: <https://doi.org/10.2903/sp.efsa.2012.EN-300>
- Vásquez-Caicedo AL, Bell S and Hartmann B (EuroFIR), 2008. Report on collection of rules on use of recipe calculation procedures including the use of yield and retention factors for imputing nutrient values for composite foods