Annex to: EFSA NDA Panel, 2024. Scientific opinion on the tolerable upper intake level for preformed vitamin A and β-carotene. doi.org/10.2903/j.efsa.2024.8814

Annex G – Additional information requested and decisions taken for the assessment

Publication	Information requested from the authors	Authors' reply and decision taken
Barker et al. (2005)	Summary statistics on intakes from supplements (from cod liver oil and multivitamin supplements) among cases and controls. Additionally, also the summary statistics for serum retinyl palmitate for all categories of intake.	Some raw date was provided but it was not possible to calculate the intake estimates from supplements or the concentrations for the different quartiles of serum retinyl palmitate. The study was included in the assessment with the available information reported in the publication.
Bille et al. (2007)	To clarify whether the results presented pertain to preformed or total vitamin A (i.e., including beta carotene supplements) supplementation.	The study authors confirmed the results pertain to preformed vitamin A supplementation.
Rejnmark et al. (2004)	Number of fracture cases per quintile of preformed vitamin A	The study authors no longer had access to the data. Study was kept in the assessment and the analyses on categories of intake for which we had the number of cases was used.
Michaëlsson et al. (2003)	To clarify what the exposure "vitamin A" entails. The means, standard deviations and quintile limits for vitamin A intake (with and without supplements). If available, to provide the analysis for the middle quintiles, the number of participants per quintile and number of fractures per quintile.	The study authors clarified the two vitamin A exposures refer to preformed vitamin A from background diet only and preformed vitamin A from diet and supplements. They also provided the means, SDs and quintile limits. They were not able to provide the analysis for the middle quintiles (Q2-4) or the number of participants and number of cases per quintile. The study was included in the assessment.
Lim et al. (2004)	The means and standard deviations for the vitamin A intake categories that were reported as ranges, with the lowest and highest category reported as open categories.	The study authors no longer had access to the data. The study was included in the assessment and the analyses on quintiles of intake for which the ranges and means were available was used.

Kaptoge et al. (2003)	To clarify what the exposure "vitamin A" entail and the mean intakes per tertile.	No response received. As exposure was reported in mcg/d only, with separate intake reported for β-carotene, this information taken together with the means reported for the population sampled, it was assumed the term "vitamin A" refers to preformed vitamin A only.
Macdonald et al. (2004)	Baseline carotenoid intake levels	The study authors no longer had access to the data. Study was kept in the assessment for the analysis on preformed and total vitamin A.
Key et al. (2007)	The total number of women and men per category of retinol intake. If available, the mean, standard deviation, and range of intake per retinol category. To clarify whether the estimated retinol intakes in the study was from food only or if the amount from supplements was also considered.	The requested data was provided by the study authors though it was based on an updated dataset that included ~1000 participants more (total n=35702). The study authors stated that the mean and SD would not have substantially changed with the additional participants. It was clarified that the estimated intakes are from food only.
Ambrosini et al. (2013)	The results of the analysis for fracture risk for the 1st phase of the intervention study when participants were receiving either retinyl esters or beta-carotene.	No response received from the study authors. Phase 1 of the study was a randomized controlled trial where subjects were supplemented with either retinyl esters or β-carotene. The study was excluded from the assessment as it only reports on phase 2 of the trial and did not fulfil eligibility criteria.
de Jonge et al. (2015)	To clarify whether the risk estimates presented in Figure 2b are hazard ratios and accompanying 95% CIs for the quintiles of total dietary vitamin A intake and retinol intake, and whether these are energy-adjusted. The number of non-cases (or total study participants) in each quintile of energy-adjusted total vitamin A and retinol. The range of intake for each quintile of energy-adjusted total vitamin A and retinol.	The study authors clarified the estimates refer to hazard ratios and confirmed the use of energy adjusted quintiles. The number of cases and total participants was available in a supplementary table. The range of intakes was not available and would require new analysis. The information provided was used in the assessment.
White et al. (2006)	To clarify whether vitamin A supplements reported in the paper included beta-carotene or retinol only.	The study authors clarified that participants were asked to report on the vitamin A content of the supplement, but given that the assessment was carried out in the early 1980s they assume these were retinol supplements. The exposure was categorized as preformed vitamin A in the assessment.
Hayhoe et al. (2017)	To provide the analyses for retinol intake from diet and supplements for risk of	The requested data was provided and included in the assessment.

	fracture. To provide the risk estimates for the middle quintiles (Q2-5) for the diet analyses. To provide mean retinol intakes for the quintiles of intake.	

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