# Health based guidance values

## In this guide



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51. For vitamin D, EFSA established a tolerable upper intake level (UL) of 100 µg vitamin D/day, for adults (including pregnant and lactating women) and

adolescents aged 11-17 years (EFSA, 2012). The UL covers all sources of dietary intake. In 2023, EFSA reconfirmed this 100 µg/day UL but expanded the definition to vitamin D equivalents (VDE), also for adults (including pregnant and lactating women) and adolescents aged 11-17 years. EFSA proposed a factor of 2.5 for the conversion of calcidiol monohydrate into vitamin D3, for labelling purposes. The conversion factor accounts for its greater ability to increase serum 25(OH)D concentrations compared to vitamin D3, for doses up to 10 µg/day. (EFSA, 2023a).

52. The COT agreed with the UL for vitamin D and VDE (COT, 2014; COT, 2022). **As discussed in the Statement on the potential effects of excess vitamin D intake during preconception, pregnancy and lactation, the TUL does not cover individuals who may be more vulnerable to the adverse effects of vitamin D such as those with genetic predispositions (COT, 2022).**

53. **In EFSA's scientific and technical assistance to the evaluation of the safety of calcidiol monohydrate as a novel food, EFSA noted "that safety had been established up to 10 µg/day for these population groups (EFSA NDA Panel, 2021), which corresponds to 25 µg VDE/day considering a CF for calcidiol monohydrate into vitamin D3 of 2.5" (where CF is conversion factor) (EFSA, 2024).**

54. EFSA stated the following reasons for their conclusions on the safety of calcidiol monohydrate under the proposed conditions use and use up to 10 µg/day for adolescence and adults (including pregnant and lactating women):

I) "calcidiol monohydrate did not raise serum 25(OH)D concentrations above 107 nmol/L and did not increase the risk of hypercalcaemia, hypercalciuria or other adverse health effects at doses up to 10 µg/day in RCTs. The duration of the intervention ranged from 4 weeks to 12 months, depending on the study; and

II) conservative, total combined vitamin D intake estimates from calcidiol (NF + background diet) and vitamin D (highest P95) from the background diet (up to 70.2 and 78.5 µg/day for adolescents and adults, respectively) were well below the UL for adolescents and adults, including pregnant and lactating women (100 µg/day)"

55. However, the ACNFP applied the 2.5 conversion factor to the TUL of 100 µg/day for vitamin D, and calculated calcidiol to have an adjusted upper intake of 40 µg/day for adults (ACNFP, 2024). The COT are in agreement with the ACNFP's upper intake level of 40 µg/day, which is greater than the level that EFSA

established as safe (i.e.  up to 10 µg/day). The COT were uncertain if the level EFSA established as safe was due to the proposed use of the regulated product assessed being only up to 10 µg/day of it was derived by other means.