

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment

Statement on Vitamin D Exposure Levels in Formula Fed Infants and Children: Lay Summary

1. The main sources of vitamin D for infants (0 to 12 month-olds) and young children (1 to 4 year-olds) are through exposure to sunlight, ingestion of supplements, and consumption of formulae (baby milks) that are fortified with vitamin D. Infant formula is suitable from birth, whilst follow-on formula is suitable for infants from 6 months of age, as communicated via the [NHS.uk website](https://www.nhs.uk).
2. Current UK government advice ([NHS advice on vitamin D](https://www.nhs.uk)) recommends that babies who are being breast-fed should receive a supplement containing 8.5-10 µg/d vitamin D from birth to 1 year of age, and 10 µg/d for ages 1 up to 4 years of age. Babies fed infant formula should not be given a vitamin D supplement if they consume more than 500 ml/day as formula is already fortified with vitamin D and this ensures that they do not consume too much.
3. In 2006, the European Commission established a minimum vitamin D content in infant- and follow-on formulae of 1 µg per 100 kcal (Directive 2006/141/EC). Subsequently in 2016, in Commission Delegated Regulation 2016/127, this was doubled to 2 µg per 100 kcal. This new regulation became applicable in Great Britain from the 1st of January 2021 and currently remains applicable. EU legislation on nutrition continues to be directly applicable in Northern Ireland.
4. In order to inform discussion across the four nations on whether existing advice around vitamin D supplements remains appropriate or needed updating in light of the increase in the minimum vitamin D content of infant- and follow-on formula the FSA conducted an exposure assessment to determine whether this increase could result in infants (0-12 month-olds) and young children (1-4 year-olds) exceeding their recommended tolerable upper levels (TULs) for vitamin D. TULs are the maximum levels of a nutrient that can be consumed every day for a long period of time without adverse health effects occurring. For infants (birth to 6 months of age) the TUL for vitamin D is 25 µg per person daily; for infants (6 to 12 months of age) the TUL is 35 µg per person daily; and for children aged 1 to 4 years the TUL is 50 µg per person daily.
5. This statement provides an exposure assessment for infants and young children, regarding their vitamin D intake from infant formula products, vitamin D supplements,

and food (including breast milk) compared to the relevant TULs established by the European Food Safety Authority (EFSA), one of which had been revised up from 25 µg/day in 2018. The Committee agreed with the revised EFSA TUL of 35 µg/person/day for 6-12 month-olds.

6. The Committee concluded that the new minimum vitamin D content in infant formulae did not lead to excessive vitamin D exposure in infants or young children, as minor exceedances of their respective TULs occurred only when, in combination with other sources such as the recommended supplements, the quantities of infant formula consumed reached 1000 ml.

7. The Committee noted that UK government guidance on vitamin D supplementation includes consideration of the nutritional recommendations of the Scientific Advisory Committee on Nutrition (SACN) to ensure that infants and young children receive sufficient Vitamin D. It would therefore not be appropriate for the COT to make any specific recommendation for a change in the UK guidance, based purely on consideration of the possibility of adverse effects from high intakes. However, the Committee did conclude that the mandatory increase in the minimum vitamin D content of infant and follow-on formula to 2 µg/100 kcal did not give rise to any toxicological concerns for human health.

8. The full COT statement can be found on the COT website:
Statement on vitamin D exposure levels in formula fed infants and children.

Lay Summary to COT Statement 02/2024