Risk characterisation - Statement on vitamin D Exposure Levels in Formula Fed Infants and Children

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28. **Infants (6 months old):** Chronic exposures to vitamin D from food (including breast milk) and consumption of infant formulae have been estimated for 4 – 6 month-olds (Tables 9 & 10). For 4 - 6 month-olds, there are no exceedances of the TUL of 25 µg/day at the mean, 97.5th percentile, or maximum

estimated levels of exposure. However, infants may have additional exposure to vitamin D through consumption of supplements. Therefore, if an additional vitamin D intake of 10 µg/day is added (highest recommended intake from a vitamin D supplement) (data not shown), then there would be exceedances of the TUL of 25 µg/day, but only at and above the 97.5th percentile, i.e. infants consuming foods at or above the 97.5th percentile, including maximum vitamin D concentrations permitted in infant formula.

29. Additionally, Table 5 shows the estimates of combined exposure from ingestion of infant formulae, food (including breast milk), and supplements (for 0 - 6 month-olds). There are only slight exceedances of the TUL of 25 µg/day for infants up to 6 months old, and only when 1000 ml or more of infant formulae are consumed daily at the maximum vitamin D limits of 2.5 µg/100 kcal (Table 5, values shown in bold).

30. **Infants (6 - 12 month-olds):** Chronic exposures to vitamin D from food (including breast milk) and consumption of infant formulae have been estimated for 6 - 12 month-olds (Tables 9 & 10). For 6 - 12 month-olds, there are no exceedances of EFSA's TUL of 35 µg/day. However, if an additional vitamin D intake of 10 µg/day is added (highest recommended intake from a vitamin D supplement) (data not shown), then there would be an exceedance of EFSA's TUL of 35 µg/day, but only at the maximum estimated exposure.

31. Additionally, Table 6 shows estimates of combined exposure from ingestion of follow-on formula, food (including breast milk), and supplements (for 6 - 12 month-olds). There are slight exceedances of EFSA's TUL of 35 µg/day in this Table, but only when 1000 ml or more of infant formulae are consumed daily at the maximum vitamin D limits of 3 µg/100 kcal.

32. **Children aged 1 to 4 years (12 - 18 months and 18 - 48 months old):** Table 7 gives a scenario-based combined exposure to vitamin D in toddler milks, food (including breast milk), and supplements for 1-4 year-olds. This exposure assessment uses a range of vitamin D concentrations in toddler milks available on the UK market, which are derived from label information. A number of these products contain much higher levels of vitamin D per 100 kcal compared with infant and follow-on milks (Table 2, Annex B). Table 1, Annex B indicates that children aged 1 to 4 years generally consume less than 500 ml of fortified milk per day; as such, they are likely to ingest vitamin D supplements as well. As shown in Table 7, estimates of combined exposure from ingestion of toddler milks, food (including breast milk), and supplements exceed the TUL of 50 µg/day for children aged 1 to 4 years, but only when 1000 ml or more of toddler milk are

consumed daily at the maximum vitamin D limits of 6.27 µg/100 kcal.