

Additional information to First draft statement on vitamin D exposure levels in formula fed infants and children

Scenario-based combined exposure to vitamin D from infant formula and supplements

1. As noted in the cover paper, the background exposure assessment for 1-4 year-olds was not initially included in the first draft statement. However, this exposure assessment is now provided in amended Tables 5-7 below.
2. According to the current guidance on vitamin D, it is recommended that infants consuming less than 500 ml of infant formula per day should have additional exposure from consumption of vitamin D supplements. Therefore, estimates of combined exposure to vitamin D from supplements, other dietary foods, and infant formula (Table 5) or follow-on formula (Table 6) were calculated. These estimates are calculated for the daily vitamin D exposure per person, given the quantity of formula consumed.
3. The following amended Tables (5-7) use the 97.5th percentile for estimated food consumption rates, to help provide a conservative assessment of exposure. The occurrence data used for estimation of exposure to vitamin D from consumption of other foods is described in Annex C. This includes consumption of breast milk, using occurrence data where the mother was taking a vitamin D supplement, which also helps to provide a conservative assessment of exposure.

Table 5: Scenario-based combined exposure to vitamin D from ingestion of infant formulae, food, and supplements (for 0-<6 month-olds).

Daily consumption (ml)**	Daily kcal consumed*	Vitamin D exposure from formulae µg/day*	Exposure from food (P97.5) (µg/day)*	Exposure from supplements (µg/day)*	Minimum combined exposure (µg/day)*	Maximum combined exposure (µg/day)*
100	67	1.3 – 1.7	2.9	3.5	7.7	8.1
100	67	1.3 – 1.7	2.9	8.5	13	13

100	67	1.3 – 1.7	2.9	10	14	15
200	130	2.7 – 3.4	2.9	3.5	9.1	9.8
200	130	2.7 – 3.4	2.9	8.5	14	15
200	130	2.7 – 3.4	2.9	10	16	16
300	200	4.0 – 5.0	2.9	3.5	10	11
300	200	4.0 – 5.0	2.9	8.5	15	16
300	200	4.0 – 5.0	2.9	10	17	18
400	270	5.4 – 6.7	2.9	3.5	12	13
400	270	5.4 – 6.7	2.9	8.5	17	18
400	270	5.4 – 6.7	2.9	10	18	20
500	340	6.70 – 8.4	2.9	3.5	13	15
500	340	6.7 – 8.4	2.9	8.5	18	20
500	340	6.7 – 8.4	2.9	10	20	21
1000	670	13 – 17	2.9	3.5	19	23
1000	670	13 - 17	2.9	8.5	24	28
1000	670	13 - 17	2.9	10	26	30

Values are to 2 significant figures

*Using an average of 67 kcal /100 ml, the concentration of vitamin D in infant formula were derived, given the minimum and maximum vitamin D concentrations of 2 and 2.5 µg/100 kcal permitted in infant formula. Values shown in bold are those which exceed the TUL of 25 µg/day for 0-6 month-olds.

**It is usually indicated on products for toddler’s formula that 2 x 150 ml provides the daily recommended intake, therefore exposure scenarios where daily consumption ≥ 400 ml are unlikely to be representative of actual consumption.

Table 6: Scenario-based combined exposure to vitamin D from ingestion of follow-on formula, food, and supplements (for 6-<12 month-olds).

Daily consumption (ml)**	Daily kcal consumed*	Vitamin D exposure from formulae µg/day*	Exposure from food (P97.5) (µg/day)	Exposure from supplements (µg/day)	Minimum combined exposure (µg/day)	Maximum combined exposure (µg/day)
100	67	1.3 - 2.0	9.3	3.5	14	15

100	67	1.3 - 2.0	9.3	8.5	19	20
100	67	1.3 - 2.0	9.3	10	21	21
200	134	2.7 - 4.0	9.3	3.5	16	17
200	134	2.7 - 4.0	9.3	8.5	21	22
200	134	2.7 - 4.0	9.3	10	22	23
300	201	4.0 - 6.0	9.3	3.5	17	19
300	201	4.0 - 6.0	9.3	8.5	22	24
300	201	4.0 - 6.0	9.3	10	23	25
400	268	5.4 - 8.0	9.3	3.5	18	21
400	268	5.4 - 8.0	9.3	8.5	23	<u>26</u>
400	268	5.4 - 8.0	9.3	10	25	<u>27</u>
500	335	6.7 – 10	9.3	3.5	20	23
500	335	6.7 – 10	9.3	8.5	25	<u>28</u>
500	335	6.7 – 10	9.3	10	<u>26</u>	<u>29</u>
1000	670	13 – 20	9.3	3.5	<u>26</u>	<u>33</u>
1000	670	13 – 20	9.3	8.5	<u>31</u>	38
1000	670	13 - 20	9.3	10	<u>32</u>	39

Values are to 2 significant figures

*Using an average of 67 kcal /100 ml, the amount of vitamin D in follow-on formula were derived, given the minimum and maximum vitamin D concentrations of 2 and 3 µg/100 kcal permitted in follow-on formula. Underlined values are those which exceed the EFSA's previous TUL of 25 µg/day for 6-12 month-olds. Values in bold are those which exceed EFSA's revised TUL of 35 µg/day for 6-12 month-olds.

**It is usually indicated on products for toddler's formula that 2 x 150 ml provides the daily recommended intake, therefore exposure scenarios where daily consumption ≥ 400 ml are unlikely to be representative of actual consumption.

4. Table 7 shows estimates of combined exposure to vitamin D (i.e. exposure from ingestion of growing up/toddler milks, food, and from vitamin D supplements) in young children aged 1 to 4 years.

Table 7: Scenario-based combined exposure to vitamin D in toddler milks, food, and supplements (for 1-4 year-olds).

Daily consumption (ml)**	Daily kcal consumed*	Vitamin D exposure µg/day*	Exposure from food (P97.5) (µg/day)	Exposure from supplements (µg/day)	Minimum combined exposure (µg/day)	Maximum combined exposure (µg/day)
100	67	1.1 - 3.7	17	3.5	22	24
100	67	1.1 - 3.7	17	8.5	27	29
100	67	1.1 - 3.7	17	10	28	31
200	134	2.2 - 7.4	17	3.5	23	28
200	134	2.2 - 7.4	17	8.5	28	33
200	134	2.2 - 7.4	17	10	29	34
300	201	3.3 - 11	17	3.5	24	32
300	201	3.3 - 11	17	8.5	29	37
300	201	3.3 - 11	17	10	30	38
400	268	4.4 - 15	17	3.5	25	36
400	268	4.4 - 15	17	8.5	30	41
400	268	4.4 - 15	17	10	31	42
500	335	5.5 - 19	17	3.5	26	40
500	335	5.5 - 19	17	8.5	31	45
500	335	5.5 - 19	17	10	33	46
1000	670	11 - 37	17	3.5	32	58
1000	670	11 - 37	17	8.5	37	63
1000	670	11 - 37	17	10	38	64

Values are to 2 significant figures

*Using an average of 67 kcal /100 ml, exposures to vitamin D from selected growing up and toddler milk available on the UK market were combined with exposures from vitamin D supplements. The exposure estimates employed minimum and maximum vitamin D concentrations of 1.64 and 6.27 µg/100 kcal of growing up/toddler milks. Values shown in bold are those which exceed the EFSA's TUL of 50 µg/day for children aged 1 to 4 years.

**It is usually indicated on products for toddler's formula that 2 x 150 ml provides the daily recommended intake, therefore exposure scenarios where daily consumption ≥ 400 ml are unlikely to be representative of actual consumption.

