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

In this guide

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15. In order to inform discussion across the four nations on whether existing advice around vitamin D supplements remains appropriate or needs updating, in light of the increase in the minimum vitamin D content of infant- and follow-on formulae, the FSA has conducted an exposure assessment to determine

whether this increase could cause infants and children to exceed their respective TULs (with and without additional exposure from vitamin D supplements).

16. Vitamin D exposures from infant and follow-on formulae were calculated from UK consumption data and vitamin D concentrations in these products.

17. Chronic consumption data for infant formulae were taken from the 2011 Diet and Nutrition Survey of Infants and Young Children (DNSIYC) (DH, 2013) and the rolling National Dietary and Nutrition surveys (NDNS) years 1-11 (Bates *et al*., 2014, 2016, 2020; Roberts *et al*., 2018) (Table 1, Annex B). The vitamin D concentration was based on a representative selection of vitamin D-containing formulae (Table 2, Annex B).

Exposure estimates based on the new regulation:

18. Using the minimum and maximum vitamin D concentrations stated in Commission Delegated Regulation 2016/127 (Table 1), with an average calorie content of 67 kcal/100 ml of infant formula (from values in Table 2, Annex B), the following vitamin D concentrations in infant and follow-on formulae were estimated:

- minimum and maximum vitamin D concentrations of 1.34 µg/100 ml and 1.68 µg/100 ml in infant formula, respectively; and,
- minimum and maximum vitamin D concentrations of 1.34 and 2.01 µg/100 ml in follow-on formula, respectively.

19. Table 2 shows the estimated chronic exposures to vitamin D for 4 – 12-month-olds from consumption of infant formula. These estimates make use of the minimum vitamin D content of 2 µg/100 kcal in infant formulae as stated in Commission Delegated Regulation 2016/127 (the new regulation).

Table 2: Estimates of chronic exposure to vitamin D for 4 – 12 month-olds from consumption of infant formula (based on the new regulation for infant formula; without supplements) (µg/person/day).

Age group (months)	**Number of consumers**	**Mean ***	**97.5th percentile ***	**Maximum ***

4 - 6	92	8.5 - 11	13 - 17	15 - 19
6 - 12	874	6.5 – 9.8	12 - 18	20 - 29
4 - 12	966	6.7 - 10	12 - 18	20 - 29

* Uses minimum and maximum vitamin D concentrations of 1.34 µg/100 ml and 2.01 µg/100 ml, respectively. Rounded to two significant figures.

Exposure estimates based on infant formula products currently available on the UK market.

20. Chronic exposures to vitamin D were also estimated for infant and follow-on formula products, ‘toddlers’ milks’ and ‘growing up milks’ currently available on the UK market, using concentrations of vitamin D in these products. These exposure estimates are shown in Table 3.

Table 3: Estimates of chronic exposure to vitamin D from consumption of infant formula products currently available on the UK market (without supplements) (µg/person/day).

Age group	**Concentration used (µg/100kcal)**	**Number of consumers**	**Mean ***	**97.5th Percentile ***	**Maximum ***
4 - 6 months	2.20 - 2.5	92	9.2 - 10	15 - 17	17 - 19
6 - 12 months	2.54	874	8.3	15	25
12 - 18 months	1.64 - 5.0	260	4.0 - 12	8.4 - 26	9.9 - 31

18 - 48 months	1.64 - 6.27	32 #	3.6 - 12	8.2 - 28	8.9 - 30
4 - 12 months	2.20 - 2.54	966	7.3 – 8.5	13 - 16	21 - 25

* Rounded to 2 significant figures.

Consumption or exposure estimates made with a small number of consumers may not be accurate. As the number of consumers is less than 60, this estimate should be treated with caution and may not be representative for a large number of consumers.

Exposure assessment (supplements only):

21. As noted in paragraph 7, it is currently advised that babies from birth to 1 year of age who are being breastfed should be given a daily supplement containing 8.5 to 10 µg of vitamin D. Therefore, an exposure assessment was conducted to estimate levels of vitamin D exposure in infants through consumption of vitamin D supplements (without infant formulae) (Table 4). These estimates make use of the vitamin D content of some supplements currently available on the UK market (Table 3, Annex B).

Table 4: Summary of infants' and toddlers' estimated exposure to vitamin D through consumption of supplements only.

Age group	**Daily vitamin D supplement exposure (µg/day)**
4 - 6 months	3.5 - 10
6 - 12 months	3.5 - 10
12 - 18 months	3.5 - 10

18 - 48 months 3.5 - 10

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

22. Table 5 shows different exposure scenarios for vitamin D, comparing individual and multiple sources. The chronic consumption rates used for the assessment for infants are shown. According to the current guidance on vitamin D (see paragraph 7), 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 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.

23. 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, food (including breast milk), 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.

24. The following Tables (5-7) use the 97.5^{th} 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 B. This includes consumption of breast milk, using occurrence data where the mother was taking a vitamin D supplement, which also helps to ensure a conservative assessment of exposure.

Table 5: Scenario-based combined exposure to vitamin D from ingestion of infant formulae, food (including breast milk), 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 calculated, 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 is ≥ 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 (including breast milk), 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	26
400	268	5.4 - 8.0	9.3	10	25	27
500	335	6.7 – 10	9.3	3.5	20	23
500	335	6.7 – 10	9.3	8.5	25	28
500	335	6.7 – 10	9.3	10	26	29
1000	670	13 – 20	9.3	3.5	26	33
1000	670	13 – 20	9.3	8.5	31	**38**

1000	670	13 - 20	9.3	10	32	**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. Values in bold are those which exceed EFSA's 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 is ≥ 400 ml are unlikely to be representative of actual consumption.

25. 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 (including breast milk), 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 is ≥ 400 ml are unlikely to be representative of actual consumption.

Exposure assessment from food (including breast milk)

Occurrence and consumption data

26. An exposure assessment was conducted to estimate chronic infant exposures to vitamin D from food (including breast milk). In terms of the occurrence data used for this exposure assessment, Table 8 gives an overview of the vitamin D levels present in a variety of different foods that could be consumed by an infant. Foods were selected which are known to contain higher levels of vitamin D. The levels used are largely based on a report published by SACN (SACN, 2016). The consumption data used for the exposure assessment is from the 2011 Diet and Nutrition Survey of Infants and Young Children (DNSIYC) (DH, 2013) and the rolling National Dietary and Nutrition surveys (NDNS) years 1-11 (Bates *et al.,* 2014, 2016, 2020; Roberts *et al*., 2018). Maximum consumption rates have been included to help estimate a worst-case scenario. Additional details on the derivation of the vitamin D levels in specific food groups (breast milk, mushrooms, egg yolk, oily fish, animal meat and fat, animal offal and food products voluntarily fortified with vitamin D), as well as the consumption rates used for the exposure assessment, are provided in Annex B.

Table 8: Estimates of chronic exposure of infants (aged 4 to 12 months) to vitamin D from consumption of some foods.

Food type (number of consumers)	**Mean consumption (g/day)**	**97.5th percentile consumption (g/day)**	**Estimated vitamin D concentration (µg/kg)**	**Mean exposure (µg/person/day) ***	**97.5th percentile exposure (µg/person ***
Breast milk ^	480	1200	2	0.12	0.29

Mushrooms (298)	2.7	13	Min: 2.1	0.0057	0.028
Mushrooms (298)	2.7	13	Max: 100	0.27	1.3
Eggs (292)	3.7	14	130	0.47	1.7
Oily fish (167)	7.3	24	Min: 50	0.37	1.2
Oily fish (167)	7.3	24	Max: 160	1.2	3.9
Chicken (930)	7.6	27	Min:1	0.0076	0.027
Chicken (930)	7.6	27	Max: 15	0.11	0.41
Beef (847)	7.7	30	Min:1	0.0077	0.030
Beef (847)	7.7	30	Max: 15	0.11	0.45
Pork (451)	7.1	27	Min: 1	0.0071	0.027
Pork (451)	7.1	27	Max: 15	0.11	0.40
Turkey (60)	6.0	17	Min:1	0.0060	0.017
Turkey (60)	6.0	17	Max:15	0.091	0.26

Offal- liver and kidney (17) *	5.9	19	Min:1	0.0059	0.019
Offal- liver and kidney (17) *	5.9	19	Max:15	0.089	0.28
Margarine and spreads (426)	2.8	9.6	Min: 50	0.14	0.48
Margarine and spreads (426)	2.8	9.6	Max: 75	0.21	0.72
Breakfast cereals (519)	13	56	Min: 25	0.31	1.4
Breakfast cereals (519)	13	56	Max: 84	1.1	4.7
Dried milk (464)	1.6	10	Min: 1.5	0.0024	0.015
Dried milk (464)	1.6	10	Max: 46	0.074	0.46
Evaporated milk (2 *)	1.2	1.3	Min: 26	0.032	0.033

Evaporated milk (2 *)	1.2	1.3	Max: 29	0.035	0.037
Plant-based drinks (750) **	79	532	Min: 7.5	0.59	4.0
Plant-based drinks (750) **	79	532	Max: 18	1.4	9.6

Values are to 2 significant figures.

^ This assumes a breastfeeding mother does not consume supplements.

* Consumption or exposure estimates made with a small number of consumers may not be accurate. As the number of consumers is less than 60, this estimate should be treated with caution and may not be representative for a large number of consumers.

** Cow’s milk has been used as a proxy for plant-based drinks consumption. Cow’s milk contains very low amounts of vitamin D (approximately 1 µg/kg). As such, the exposure may be overestimated as it is expected that only a low number of infants and toddlers would consume plant-based drinks in place of cow’s milk.

27. Tables 9 and 10 below provide estimates of chronic exposure to vitamin D from consumption of infant formula/follow-on milk (which are based on minimum and maximum vitamin D concentrations from Commission Delegated Regulation 2016/127) and food (including breast milk). The ranges of vitamin D exposure in these tables were estimated by taking account of the following:

- the estimated range of concentrations of vitamin D in infant and follow-on formula;
- the estimated rates of consumption; and,
- minimum and maximum vitamin D levels in various other food products (including breast milk) as described above.

Table 9: Estimates of chronic infant exposure to vitamin D from consumption of food and infant formula/follow-on milk (based on Commission Delegated Regulation 2016/127) and breast milk (where the mother is supplementing with vitamin D (2 µg vitamin D /kg breast milk).

Age group	**Number of consumers**	**Mean chronic exposure to vitamin D (µg/person/day) ***	**97.5th percentile chronic exposure to vitamin D (µg/person/day) ***	**Maximum chronic exposure to vitamin D (µg/person/day) ***
4 - 6 months	113	7.2 - 11	14 -21	15 -23
6- 12 months	1286	5.3 – 8.6	12 -18	20 - 30
4 - 12 months	1399	5.4 – 8.7	12 - 19	20 - 30

Values are to 2 significant figures.

* Assumes 1 L = 1 kg breast milk.

Table 10: Estimates of chronic infant exposure to vitamin D from consumption of food and infant formula/follow-on milk (based on Commission Delegated Regulation 2016/127) and breast milk (where the mother is not supplementing with vitamin D (0.25 µg vitamin D /kg breast milk).

Age group	**Number of consumers**	**Mean chronic exposure to vitamin D (µg/person/day) ***	**97.5th percentile chronic exposure to vitamin D (µg/person/day) ***	**Maximum chronic exposure to vitamin D (µg/person/day) ***

4 - 6 months	113	6.8 – 10	14 -21	15 -23
6 - 12 months	1286	5.1 – 8.4	12 -18	20 - 30
4 - 12 months	1399	5.2 – 8.5	12 - 19	20 - 30

Values are to 2 significant figures.

* Assumes 1 L = 1 kg breast milk.