TOX/2022/27

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

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

Introduction

1. This first draft statement provides an exposure assessment for infants and young children, regarding their vitamin D intake from infant formulae products, vitamin D supplements, and other dietary sources.

2. This work has been requested by the Nutrition, Labelling, Composition and Standards (NLCS) because the minimum vitamin D level permitted in infant- and follow-on formulae has been increased from 1 to 2 µg per 100 kcal. The NLCS wish to know whether the current UK government guidelines, with respect to consumption of vitamin D supplements, is still correct, following this increase in minimum vitamin D levels in formulae.

3. These estimates of exposure are subsequently compared against the corresponding tolerable upper levels (TULs) for vitamin D for infants and children for risk characterisation purposes. The draft statement is provided in annex A, whilst Annex B provides a summary of EFSA's vitamin D TUL for 6-12 month-olds, which in 2018 was increased from 25 µg/day to 35 µg /day. Annex C provides a table of some common infant formula products and vitamin D supplements available on the UK market, in addition to descriptions of the occurrence data used regarding vitamin D in other dietary sources.

4. The background exposure assessment for 1-4 year-olds is not included in this draft statement, but will be provided as soon as it is available.

Questions on which the views of the Committee are sought

5. Members are requested to consider the information provided in the draft statement and answer the following questions:

i. Does the Committee agree with EFSA's revised TUL of 35 µg/person/day for 6 - <12 month-olds?
ii. Does the Committee consider that the new minimum vitamin D content in infant formulae leads to excessive vitamin D exposure in infants?
iii. If so, does the Committee consider that the current UK government guidance on vitamin D supplementation for infants needs updating?

Secretariat

May 2022

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

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

Background

1. The FSA received a request from the Nutrition, Labelling, Composition and Standards (NLCS). They would like to seek a view on the potential risk of vitamin D toxicity in infants and children up to 4 years old, consuming infant and follow-on formula as a result of the increase in the minimum vitamin D content of both. This increase is due to a change in the regulations. The maximum vitamin D content for both has remained the same.

2. The outcome of the analysis will inform further discussion across the four nations on whether existing advice around vitamin D supplementation for infants consuming formula remains appropriate, or whether this needs to be updated.

3. The Scottish Government is liaising with the FSA to ensure that their current advice on universal vitamin D supplementation is appropriate following the change in the minimum vitamin D content of infant and follow-on formulae. The potential impact this might have on the current UK government advice on vitamin D supplementation is also considered.

Introduction

4. 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 that are fortified with vitamin D.

5. Current UK government advice on vitamin D supplementation is based on recommendations made by the Scientific Advisory Committee on Nutrition (SACN) in its report entitled ‘Vitamin D and health’ (SACN, 2016).

6. 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.

7. In the UK, it is currently advised via the NHS 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 (regardless of whether the mother is taking a vitamin D supplement);
- babies should not be given a vitamin D supplement if they are having more than 500 ml of infant formula per day, because infant formula is fortified with vitamin D and other nutrients; and
- children aged 1 to 4 years old should be given a daily supplement of 10 µg of vitamin D.”

Limits for vitamin D content in infant and follow-on formulae

8. 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 (the rationale for this change was not included in the Regulation document). This new regulation became applicable in Great Britain from the 1st January 2021, and the new limits are shown in Table 1. EU legislation on nutrition continues to be directly applicable in Northern Ireland.

9. ‘Toddlers’ milks’ and ‘growing up milks’ are not regulated as infant or follow-on formulae and do not fall under the remit of Commission Delegated Regulation (EU) 2016/128 (the legislation that has the specified maximum and minimum levels of vitamin D content) (EC, 2019). There are no specific regulations for milks for children over 12 months of age ('toddler milks' are considered to be 'general food', which just need to comply with general food law, for example in terms of allergen labelling).

10. Although the legislation is for infants, the Nutrition labelling, composition and standards (NLCS) team have asked the FSA to include up to 4 years of age in the assessment, as toddler milks are produced and advertised for the second and third years of life.

Table 1: Present limits for vitamin D content in infant and follow-on formulae.

Consumer product	**Minimum (per 100 kcal)**	**Maximum (per 100 kcal)**
Infant formula	2 µg*	2.5 µg
Follow-on formula	2 µg*	3 µg

*Previously 1 µg

Tolerable upper limits for vitamin D

11. In 2012, the European Food Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies (NDA) established tolerable upper levels (TULs) for vitamin D (EFSA, 2012), based on a risk assessment conducted in 2003 by the Scientific Committee on Food (SCF, 2003). The SCF risk assessment used hypercalcaemia as the adverse effect induced by excessive vitamin D exposure. The TULs established by EFSA in 2012 were as follows:

- For infants (birth to 1 year of age), the TUL is 25 µg per person, per day.
- For children aged 1 to 4 years, the TUL is 50 µg per person, per day.

12. In 2014, the COT published a statement on the adverse effects of high levels of vitamin D, in which the COT agreed with the TULs set by EFSA in 2012 (COT, 2014).

13. However, in 2018, based on the overall evidence, the EFSA NDA Panel kept the TUL of 25 µg/day for infants up to 6 months old, and set a new UL of 35 µg /day for infants aged 6-12 months (EFSA, 2018). A summary of EFSA's rationale for this is provided in Annex B. The TUL for toddlers above 1 year of age (50 µg per person,

per day) was not changed in EFSA's 2018 assessment following its original establishment in 2003 and confirmation in 2012.

Exposure assessment

14. 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).

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

16. Chronic consumption data for infant formula 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 C). The vitamin D concentration was based on a representative selection of vitamin D-containing formulae (Table 2, Annex C).

Exposure estimates based on the new regulation

17. 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 C), the following vitamin D concentrations in infant and follow-on formulae were derived:

- 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.

18. 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 [a]	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

19. 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**Error! Reference source not found.**. These exposure estimates are shown in Table 3.

Table 3: Estimates of chronic exposure to vitamin D from consumption of infant formulae 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 should be treated with caution and may not be representative for a large number of consumers.

Exposure assessment (supplements only)

20. 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 show 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 C).

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

21. 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.

Table 5: Scenario-based combined exposure to vitamin D from ingestion of infant formulae and supplements.

Daily consumption (ml)	**Daily kcal consumed***	**Vitamin D exposure from formulae µg/day***	**Exposure from supplements (µg/day)***	**Minimum combined exposure (µg/day)***	**Maximum combined exposure (µg/day)***
100	67	1.3 – 1.7	3.5	4.8	5.2
100	67	1.3 – 1.7	8.5	9.8	10
100	67	1.3 – 1.7	10	11	12
200	130	2.7 – 3.4	3.5	6.2	6.9
200	130	2.7 – 3.4	8.5	11	12
200	130	2.7 – 3.4	10	13	14
300	200	4.0 – 5.0	3.5	7.5	8.5
300	200	4.0 – 5.0	85	13	14
300	200	4.0 – 5.0	10	14	15
400	270	5.4 – 6.7	3.5	8.9	10
400	270	5.4 – 6.7	8.5	14	15

400	270	5.4 – 6.7	10	15	17
500	340	6.70 – 8.4	3.5	10	12
500	340	6.7 – 8.4	8.5	15	17
500	340	6.7 – 8.4	10	17	18
1000	670	13 – 17	3.5	17	20
1000	670	13 - 17	8.5	22	**26**
1000	670	13 - 17	10	23	**27**

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.

Table 6: Scenario-based combined exposure to vitamin D from ingestion of follow-on formula and supplements.

Daily consumption (ml)	**Daily kcal consumed***	**Vitamin D exposure from formulae µg/day***	**Exposure from supplements (µg/day)**	**Minimum combined exposure (µg/day)**	**Maximum combined exposure (µg/day)**
100	67	1.3 - 2.0	3.5	4.8	5.5
100	67	1.3 - 2.0	8.5	9.8	11
100	67	1.3 - 2.0	10	11	12
200	134	2.7 - 4.0	3.5	6.2	7.5
200	134	2.7 - 4.0	8.5	11	13
200	134	2.7 - 4.0	10	13	14
300	201	4.0 - 6.0	3.5	7.5	9.5
300	201	4.0 - 6.0	8.5	13	15
300	201	4.0 - 6.0	10	14	16
400	268	5.4 - 8.0	3.5	8.9	12
400	268	5.4 - 8.0	8.5	14	17

400	268	5.4 - 8.0	10	15	18
500	335	6.7 – 10	3.5	10	14
500	335	6.7 – 10	8.5	15	19
500	335	6.7 – 10	10	17	20
1000	670	13 – 20	3.5	17	24
1000	670	13 – 20	8.5	22	29
1000	670	13 - 20	10	23	30

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.

22. Table 7 shows estimates of combined exposure to vitamin D (i.e. exposure from ingestion of growing up/toddler milks, 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 and supplements

Daily consumption (ml)	**Daily kcal consumed***	**Vitamin D exposure µg/day***	**Exposure from supplements (µg/day)**	**Minimum combined exposure (µg/day)**	**Maximum combined exposure (µg/day)**
100	67	1.1 - 3.7	3.5	4.6	7.2
100	67	1.1 - 3.7	8.5	9.6	12
100	67	1.1 - 3.7	10	11	14
200	134	2.2 - 7.4	3.5	5.7	11
200	134	2.2 - 7.4	8.5	11	16
200	134	2.2 - 7.4	10	12	17
300	201	3.3 - 11	3.5	6.8	15
300	201	3.3 - 11	8.5	12	20
300	201	3.3 - 11	10	13	21
400	268	4.4 - 15	3.5	7.9	18
400	268	4.4 - 15	8.5	13	23

400	268	4.4 - 15	10	14	25
500	335	5.5 - 19	3.5	9.0	22
500	335	5.5 - 19	8.5	14	27
500	335	5.5 - 19	10	16	29
1000	670	11 - 37	3.5	15	41
1000	670	11 - 37	8.5	20	46
1000	670	11 - 37	10	21	47

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.

Exposure assessment from other dietary sources

Occurrence and consumption data

23. An exposure assessment was conducted to estimate chronic infant exposures to vitamin D from other dietary sources. 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 C.

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 %ile consumption (g/day)	Estimated vitamin D concentration (µg/kg)	Mean exposure (µg/person/day)*	97.5th %ile exposure (µg/person/day)*	Max exposure (µg/person/day)*
Breast milk^	480	1200	2	0.12	0.29	0.30
Mushrooms (298)	2.7	13	Min: 2.1	0.0057	0.028	0.041
Mushrooms (298)	2.7	13	Max: 100	0.27	1.3	2.0
Eggs (292)	3.7	14	130	0.47	1.7	3.1
Oily fish (167)	7.3	24	Min: 50	0.37	1.2	2.2
Oily fish (167)	7.3	24	Max: 160	1.2	3.9	7.0
Chicken (930)	7.6	27	Min:1	0.0076	0.027	0.063
Chicken (930)	7.6	27	Max: 15	0.11	0.41	0.95
Beef (847)	7.7	30	Min:1	0.0077	0.030	0.051
Beef (847)	7.7	30	Max: 15	0.11	0.45	0.77
Pork (451)	7.1	27	Min: 1	0.0071	0.027	0.053
Pork (451)	7.1	27	Max: 15	0.11	0.40	0.80
Turkey (60)	6.0	17	Min:1	0.0060	0.017	0.020
Turkey (60)	6.0	17	Max:15	0.091	0.26	0.30
Offal- liver and kidney (17)*	5.9	19	Min:1	0.0059	0.019	0.36

Offal- liver and kidney (17)*	5.9	19	Max:15	0.089	0.28	0.36
Margarine and spreads (426)	2.8	9.6	Min: 50	0.14	0.48	1.0
Margarine and spreads (426)	2.8	9.6	Max: 75	0.21	0.72	1.5
Breakfast cereals (519)	13	56	Min: 25	0.31	1.4	5.3
Breakfast cereals (519)	13	56	Max: 84	1.1	4.7	18
Dried milk (464)	1.6	10	Min: 1.5	0.0024	0.015	0.077
Dried milk (464)	1.6	10	Max: 46	0.074	0.46	2.4
Evaporated milk (2*)	1.2	1.3	Min: 26	0.032	0.033	0.033
Evaporated milk (2*)	1.2	1.3	Max: 29	0.035	0.037	0.038
Plant-based drinks (750)**	79	532	Min: 7.5	0.59	4.0	8.4
Plant-based drinks (750)**	79	532	Max: 18	1.4	9.6	20

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. The number of consumers is less than 60, this 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. 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.

24. 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 the diet, 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 breastmilk

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 breastmilk (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 breastmilk

Risk characterisation

25. **Infants (<6 months old):** Chronic exposures to vitamin D from other dietary sources 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 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.

26. Additionally, Table 5 shows the estimates of combined exposure from infant formula and supplements. 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).

27. **Infants (6 - 12 month-olds):** Chronic exposures to vitamin D from other dietary sources and consumption of infant formulae have been estimated for 6 - 12 month-olds (Tables 9 & 10). For 6 - 12 month-olds, there is a slight exceedance of EFSA's previous TUL of 25 µg/day (which only occurs at the maximum levels of exposure), whilst there are no exceedances of EFSA's present 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 exceedances of EFSA's previous TUL of 25 µg/day, at the 97.5th percentile and maximum exposures; and
- there would be an exceedance of EFSA's present TUL of 35 µg/day, but only at the maximum estimated exposure.

28. Additionally, Table 6 which shows estimates of combined exposure from ingestion of follow-on formula and supplements. There are slight exceedances of EFSA's previous TUL of 25 µg/day for 6 - 12 month-olds, but only when 1000 ml or more of infant formulae are consumed daily at the maximum vitamin D limits of 2.5 µg/100 kcal. However, there are no exceedances of EFSA's present TUL of 35 µg/day in this Table.

29. **Children aged 1 to 4 years (12 - <18 months and 18 - <48 months old):** An exposure assessment for young children aged 1 to 4 years was included in this paper (Table 7) which was based on the range of vitamin D concentrations in toddler milks available on the UK market (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 C). Table 1, Annex C 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. However, as shown in Table 7, estimates of combined exposure from ingestion of supplements and toddler milk do not lead to any exceedances of the TUL of 50 µg/day for children aged 1 to 4 years.

Summary & conclusions

30. In this paper, infants' (0-12 month-olds) and children's (1 to 4 year-olds) exposures to vitamin D have been estimated from their consumption of infant and follow-on formulae and vitamin D supplements (alone and combination). For 0-12 month-olds, vitamin D exposure from other dietary foods has also been estimated.

31. For 0-6 month-olds, an exceedance of the TUL of 25 µg/day occurs 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). However, the Committee is reassured that this exceedance (which only occurs when infants consume ≥1000 ml of infant formula per day in addition to vitamin D supplements) occurs under an exposure scenario which goes against current NHS advice (that "babies fed infant formula should not be given a vitamin D supplement if they're consuming more than 500ml (about a pint) of infant formula a day"). Therefore, as long as the advice is followed, it is expected that infants will not exceed the TULs (given the new minimum vitamin D content used in infant formulae products).

32. As shown in Tables 9 and 10 for infants, the estimated mean and 97.5th percentile levels of chronic exposure to vitamin D (from consumption of food including breast milk, and infant formula/follow-on milk) are below the TULs of 25 µg/day (for 4-6 month-olds) and 35 µg/day (for 6-12 month-olds). If an additional vitamin D intake of 10 µg/day is added (highest recommended intake from a vitamin D supplement) (data not shown), then:

- for 4-6 month-olds, there would be exceedances of the TUL of 25 µg/day, but only at and above the 97.5th percentile exposures; and
- for 6-12 month olds, there would be exceedances of EFSA's previous TUL of 25 µg/day (at and above the 97.5th percentile exposures), and an

exceedance of EFSA's present TUL of 35 µg/day (only at the maximum estimated exposure).

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Abbreviations

DNSIYC	Diet and Nutrition Survey of Infants and Young Children
EFSA	European Food Safety Authority
Kcal	Kilocalories
Kg	Kilogram
L	Litre
NDNS	National Dietary and Nutrition survey
NHS	UK National Health Service
NLCS	Nutrition Labelling, Composition and Standards
SACN	Scientific Advisory Committee on Nutrition
SCF	Scientific Committee on Food
TUL	Tolerable Upper Level

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

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

A summary of EFSA's vitamin D tolerable upper level (TUL) for 6-12 month-olds.

1. In 2018, on the basis of the information that was available, EFSA's NDA Panel were unable to define a NOAEL for vitamin D intake (EFSA, 2018). However, the Panel identified a serum 25(OH)D concentration of ≤200 nmol/L which they considered unlikely to pose a risk of adverse health outcomes in healthy infants. This concentration was based on published studies in which no clinical symptoms suggestive of hypercalcaemia or abnormal growth were observed in infants who, following varying levels of daily vitamin D supplementation, had serum 25(OH)D concentrations >125 nmol/L (Valkama et al., 2017), >150 nmol/L (Czech-Kowalska et al., 2012; Holmlund-Suila et al., 2012), >200 nmol/L (Gallo et al., 2013), or >250 nmol/L (Grant et al., 2014).

2. In reaching the concentration value of ≤200 nmol/L, the Panel had also considered previous assessments of EFSA and other bodies that discussed 'high' serum 25(OH)D concentrations (though not specifically for infants), where the values ranged from 125 to 250 nmol/L. For example, the NDA Panel (2016) previously considered that a concentration >220 nmol/L may lead to hypercalcaemia (EFSA, 2016).

3. The Panel recognised that a 'high' serum 25(OH)D concentration is not an adverse health outcome per se, but can be considered as a surrogate endpoint. Thus, regarding the serum 25(OH)D concentration of ≤200 nmol/L, the NDA Panel

noted that this level “should not be regarded as a cut-off for toxicity but as a conservative value from which a UL could be derived”.

4. The NDA Panel used the serum concentration of 200 nmol 25(OH)D/L as the basis for establishing new TULs for infants: 25 µg/person/day for 0 - <6 month-olds, and 35 µg/day for 6 - <12 month-olds. Further details on the derivation of these TULs are provided in EFSA (2018, Annex A).

5. Briefly, the NDA Panel assessed the dose-response relationship between ‘high’ intake levels of vitamin D in a healthy population of infants (ages 0 - <12 months) and their corresponding mean serum concentrations of 25(OH)D. ‘High’ vitamin D intake levels are those that lead to ‘high’ serum concentrations of 25(OH)D.

6. These dose-response data were collected from EFSA’s systematic review of literature studies (EFSA, 2018). In these studies, however, vitamin D intakes from the background diet of 0 - <12 month-olds (i.e. from infant formulae and other fortified and unfortified foods for infants) were rarely measured or reported.

7. Therefore, the NDA Panel established their intake-response relationship for vitamin D only on the basis of the additional dose of vitamin D provided in the study, which was always through a supplement (not a fortified food).

8. The Panel therefore assumed that there is no difference in vitamin D bioavailability when supplemented, naturally present, or added to food. The same assumption was applied to the form of supplementation, e.g. as drops or pills. Indeed, the NDA Panel had previously noted in 2016 that “limited data are available on the effect of the food or supplement matrix on absorption of vitamin D (vitamin D2 or D3), and that age per se has no effect on vitamin D absorption efficiency” (EFSA, 2016).

9. The NDA Panel therefore considered that their assessment of vitamin D intakes (from supplements only) is an underestimation of infants’ actual (total) vitamin D intake. Subsequently, the Panel considered that by not including the

background intake, this leads to an “underestimation of the vitamin D dose corresponding to the UL and assessed the approach as conservative”.

10. Using a dose-response dataset derived from the literature studies that EFSA reviewed in 2018, the NDA Panel created a “mixed-effect meta-regressive model” to compute percentages of infants expected to exceed a serum concentration of 200 nmol/L of 25(OH)D following different intakes of vitamin D (between 5 and 50 µg/person/day with a step size of 5 µg). The NDA Panel concluded that this model (which uses the assumption of linearity) “seems to fit the data relatively well, except at high vitamin D intake (i.e. ≥40 µg/person/day), where most of the points systematically lie above or below the regression line”. The serum concentrations were plotted on the original (non-logarithmic) scale and also on a natural logarithmic-transformed scale.

11. As noted above, the NDA Panel considered 200 nmol/L to be a serum concentration of 25(OH)D below which adverse effects (hypercalciuria, hypercalcaemia, nephrocalcinosis, abnormal growth) would be unlikely to occur in infants.

12. These percentages are shown in Table 15 (0 - <6 month-olds) and Table 16 (6 - <12 month-olds) of EFSA’s Annex A (EFSA, 2018). These Tables indicate that at any given intake of vitamin D, 6 - <12 month-olds achieve lower serum 25(OH)D concentrations than 0 - <6 month-olds (who also have the same baseline serum 25(OH)D concentrations). This information is also shown in Tables 1-2 below.

13. For example, for 0 - <6 month-olds, based on the results of the model (original scale), at a vitamin D intake of up to 25 µg/person/day, depending on the baseline serum 25(OH)D concentration, 0 - 4 % of these individuals would achieve serum 25(OH)D concentrations >200 nmol/L (Table 1). Meanwhile, for 6 - <12 month-olds, the percentage of individuals exceeding serum 25(OH)D concentrations of 200 nmol/L would be 0 - 1 % at supplemental vitamin D intakes of up to 25 µg/person/day, and 1 - 4 % for intakes of up to 35 µg/person/day (Table 2). This information is shown below in Table 1 (0 - <6 month-olds) & Table 2 (6 - <12 month-olds), which is adapted from EFSA’s annex.

Table 1: Percentage of 0 - <6 month-olds exceeding serum 25(OH)D concentrations of 200 nmol/L (using model in original scale)

Vitamin D intake (µg/person/day)	**% infants with serum 25(OH)D concentration >200 nmol/L (using baseline concentration of 10 - 30 nmol/L)**	**% infants with serum 25(OH)D concentration >200 nmol/L (using baseline concentration of 30 - 60 nmol/L)**	**% infants with serum 25(OH)D concentration >200 nmol/L (using baseline concentration of 60 - 100 nmol/L)**
5-10	0	0	0
10-15	0	0	1
15-20	0	1	2
20-25	0	2	4
25-30	1	3	7
30-35	3	6	11

Table 2: Percentage of 6 - <12 month-olds exceeding serum 25(OH)D concentrations of 200 nmol/L (using model in original scale)

Vitamin D intake (µg/person/day)	**% infants with serum 25(OH)D concentration >200 nmol/L (using baseline concentration of 10 - 30 nmol/L)**	**% infants with serum 25(OH)D concentration >200 nmol/L (using baseline concentration of 30 - 60 nmol/L)**	**% infants with serum 25(OH)D concentration >200 nmol/L (using baseline concentration of 60 - 100 nmol/L)**
5-10	0	0	0
10-15	0	0	0
15-20	0	0	0
20-25	0	0	1
25-30	0	1	2

30-35	1	2	4

14. The NDA Panel emphasised that these exceedance percentages should not be interpreted as “precise estimates”, but rather “informed quantitative judgements”.

15. In summary, results of the NDA Panel’s analysis indicated that a larger dose of vitamin D (35 µg/person/day) is needed for 6 - <12 month-olds to have the same serum 25(OH)D concentrations as 0 - <6 month-olds (25 µg/person/day). The NDA Panel noted that this may be explained by 6 - <12 month-olds having a larger body mass than 0 - <6 month-olds (EFSA, 2018).

16. The NDA Panel had discussed whether, in their model, mean body weight or mean age was more relevant to explain serum 25(OH)D concentrations. Age was selected because age was always reported for the study participants in the literature studies reviewed, whereas body weight was sometimes missing.

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

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

1. Table 1 shows the chronic consumption rates of infant and follow-on formulae and growing-up milks in infants and young children.

Table 1: Chronic consumption rates of infant formulae for 4- to 48-month-olds of the UK population (g/person/day).

Age group	Number of consumers	Mean*	97.5th %ile*	Max*	Mean *	97.5th %ile*	Max*
4-<6 months	92	630	1000	1100	81	140	160
6-<12 months	874	490	890	1500	54	110	140
12-<18 months	260	360	770	900	34	70	90
18-<48 months	32#	330	750	810	25	46	60
4-<12 months	966	500	920	1500	56	110	160

*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 data should be treated with caution and may not be representative for a large number of consumers. Estimates are consumption-based and includes toddlers consuming infant formula, follow-on milk and growing-up milk.

2. Table 2 shows several representative infant formula products available on the UK market. The vitamin D content of these products (expressed as µg/100 kcal) was calculated from the products' label information (i.e., µg/100 ml and kcal/100 ml).

Vitamin D supplements available in the UK are listed in table 3 with their respective vitamin D content and the manufacturer's recommended daily intake.

Table 2: Common infant formula products available on the UK market and their vitamin D concentrations.

Formula type	**Vitamin D/ 100 ml (µg)**	**Kcal/ 100 ml**	**Vitamin D/ 100 kcal (µg)**
SMA PRO First Infant Milk Powder Formula Milk	1.5	67	2.24
SMA PRO Follow-on Milk Powder Formula Milk	1.7	67	2.54
SMA PRO Growing Up Milk Powder Formula Milk	1.1	67	1.64
Aptamil® First Infant Milk - 200ml Bottle	1.65	66	2.5
Aptamil® Follow On Milk - 700g Tin	1.7	68	2.5
Aptamil® Toddler Milk - 800g EaZypack	3.4	68	5
Aptamil® Toddler Baby Milk 200ml (1-2 years)	3.1	51	6.08
Aptamil® Toddler Milk - 800g EaZypack (2-3 years)	3.7	59	6.27
New Cow & Gate First Infant Formula Milk 800g	1.45	66	2.20
New Cow & Gate Follow on Formula Milk	1.7	68	2.5

800g			
Toddler Milk 800g Powder | 1-2 Years | Cow & Gate	3.4	67	5.07
Toddler Milk 800g Powder | 2-3 Years | Cow & Gate	2.6	55	4.73

Table 3: Vitamin D supplements available on the UK market for infants and toddlers.

Age group	Supplement	Vitamin D form	Recommended intake (as per label) (µg)
4-<6 months	Baby Drops Vitamin D 10ug 1.7ml | Boots	D3	10
	Abidec Immune Support 7.5ml - Boots	D3	10
	Vitabiotics Wellbaby Vit D Drops 30ml - Boots	D3	8.5
	Haliborange Multivitamin Liquid 250ml - Boots	Not stated	3.5
	Healthy Start Children's Vitamin Drops 10ml | Health | Superdrug	D3	10
	Memoraid Kids Vegan Vitamin D3 Drops 30Ml (2 Months Supply) | Superdrug	D3	10
	Abidec Multivitamin drops for babies & children 25ml – LloydsPharmacy	D2	5
6-<12 months	Vitabiotics Wellbaby Multi-Vitamin Liquid 150ml - Boots	D3	10
	Baby Ddrops Vitamin D 10ug	D3	10

	1.7ml | Boots		
	Abidec Immune Support 7.5ml - Boots	D3	10
	Vitabiotics Wellbaby Vit D Drops 30ml - Boots	D3	8.5
	Haliborange Multivitamin Liquid 250ml - Boots	Not stated	3.5
	Healthy Start Children's Vitamin Drops 10ml | Health | Superdrug	D3	10
	Memoraid Kids Vegan Vitamin D3 Drops 30Ml (2 Months Supply) | Superdrug	D3	10
	Abidec Multivitamin drops for babies & children 25ml – LloydsPharmacy	D2	5
12-<18 months	Vitabiotics Wellbaby Multi-Vitamin Liquid 150ml - Boots	D3	10
	Abidec Advanced Multivitamin Syrup Plus Omega 6 & 9 150ml - Boots	D3	7.5
	Abidec Immune Support 7.5ml - Boots	D3	10
	Vitabiotics Wellbaby Vit D Drops 30ml - Boots	D3	8.5
	Haliborange Multivitamin Liquid 250ml - Boots	Not stated	3.5
	Ddrops One Liquid Vitamin D3 10µg - 60 drops - Boots	D3	10
	Healthy Start Children's Vitamin Drops 10ml | Health | Superdrug	D3	10

	Memoraid Kids Vegan Vitamin D3 Drops 30Ml (2 Months Supply) | Superdrug	D3	10
	Abidec Multivitamin drops for babies & children 25ml – LloydsPharmacy	D2	10
month18-<48 months	Bassetts multivitamins + omega 3 3-6 Years | LloydsPharmacy	Not stated	5
	Vitabiotics Wellbaby Multi-Vitamin Liquid 150ml - Boots	D3	10
	Abidec Advanced Multivitamin Syrup Plus Omega 6 & 9 150ml - Boots	D3	7.5
	Abidec Immune Support 7.5ml - Boots	D3	10
	Vitabiotics Wellbaby Vit D Drops 30ml - Boots	D3	8.5
	Haliborange Multivitamin Liquid 250ml - Boots	Not stated	3.5
	Ddrops One Liquid Vitamin D3 10µg - 60 drops - Boots	D3	10
	Healthy Start Children's Vitamin Drops 10ml | Health | Superdrug	D3	10
	Memoraid Kids Vegan Vitamin D3 Drops 30Ml (2 Months Supply) | Superdrug	D3	10
	Abidec Multivitamin drops for babies & children 25ml – LloydsPharmacy	D2	10

3. Consumption data for the assessment of the exposure to vitamin D in infants and toddlers were obtained from DNSIYC (ages 4 -18 months) and NDNS years 1-11 (ages 1.5 to 3 years). Infant formula, breast milk, and other dietary sources were considered (Table 8, annex A). The levels of vitamin D in these foods were obtained from a variety of sources as indicated in the paper. The assessments were carried out in CRÈME, the software the FSA uses to interrogate dietary datasets. The mean, 97.5th percentile, and maximum estimates have been reported.

Breast milk

4. Consumption data for breast milk are from the DNSIYC survey; for example, for 4-<6 month-olds, mean, 97.5th percentile, and maximum daily chronic consumption rates are 690 g, 1200 g, and 1200 g, respectively. The average vitamin D concentrations in breast milk when the mother does or does not consume vitamin D supplements are 80 IU/L (equivalent to 2 µg vitamin D/kg breast milk, used for Table 9, annex A) and 10 IU/L (equivalent to 0.25 µg vitamin D/ kg breast milk, used for Table 10, annex A), respectively (Dawodu & Tsang, 2012). However, these average concentrations do not include data from UK studies.

Mushrooms

5. Wild mushrooms are a natural source of vitamin D. However, cultivated and UV treated mushrooms can also contain vitamin D. A search within the recipes database of the NDNS (Bates et al., 2014, 2016; Roberts et al., 2018) was conducted to retrieve consumption data for mushrooms and recipes containing mushrooms which had been recorded in the survey. The chronic consumption estimates for mushrooms are presented in Table 8, annex A. It is important to consider that these estimates are based on all types of cultivated mushrooms, as there are no consumption data on wild mushrooms, and it is uncertain if any of those reported in the NDNS had been treated with UV (Bates et al., 2014, 2016; Roberts et al., 2018).

6. Occurrence data for concentrations of vitamin D in mushrooms were from online sources. The minimum and maximum estimated vitamin D_2 levels for

mushrooms (cultivated and UV treated) were 2.1 µg/kg (84 IU/kg) and 100 µg/kg (4,000 IU/kg) (Cardwell et al., 2018). These were used to calculate the exposure estimates presented in Table 8, annex A. It is important to note that UV-treated mushrooms tend to have a slightly higher retail price, though consumption estimates are assumed to be similar to cultivated mushrooms.

Egg yolk

7. Natural sources of Vitamin D include egg yolk. Chronic consumption estimates of egg yolk are presented in Table 8, annex A. In order to ensure that all egg yolk consumers were included, whole egg consumption from the NDNS database was considered. On average, the egg yolk makes up 29.3 % of the edible portion of a medium egg, and 28.7 % of a large egg. The NDNS database does not specify the use of large or medium eggs, so the figure was rounded to 29 % for this paper (DH, 2013). The value of 29 % was then applied to whole egg foods to give estimates for consumption specifically of egg yolks. Foods containing solely egg whites were removed from the assessment. In Table 8, annex A, exposure estimates of vitamin D in egg yolk uses chronic consumption data and estimated vitamin D levels of 126 µg/kg (5,040 IU) (SACN, 2016).

Oily fish

8. Oily fish such as salmon, mackerel, herring and sardines are good sources of vitamin D. Estimates for chronic exposure to vitamin D in fish are presented in Table 8, annex A. Estimated minimum and maximum vitamin D levels of 50 and 160 µg/kg (2,000 and 6,400 IU) (SACN, 2016) were used to derive exposures.

Animal meat and fat

9. Further sources of vitamin D are animal meat and fat. Exposure from chicken, beef, pork and turkey were considered and are presented in Table 8, annex A. Consumption of meat and fat were considered together as fat is likely to be consumed alongside meat. Additionally, the number of consumers of animal fat alone would be very low. Exposure estimates of vitamin D were derived using chronic consumption data and estimated minimum and maximum vitamin D levels of 1 and 15 µg/kg (40 and 600 IU), respectively (SACN, 2016).

Animal offal

10. Consumption estimates of animal liver and kidney are based on overall animal offal consumption. Consumption was based on all animal offal, as liver and kidney were given as examples of offal that contain vitamin D in the 2016 SACN report and other types of offal were not specified (SACN, 2016). Exposure estimates of vitamin D_3 in animal liver and kidney were derived using chronic consumption data and estimated minimum and maximum vitamin D_3 levels of 1 and 15 µg/kg (40 and 600 IU/kg), respectively (SACN, 2016).

Food products voluntarily fortified with vitamin D

11. Foods such as margarines and fat spreads, breakfast cereals, dried and evaporated milk and plant-based drinks are voluntarily fortified with vitamin D. The estimated minimum and maximum vitamin D occurrence levels in these food products were obtained from supermarket label information. Estimates of consumption rates for these food products are presented in Table 8, annex A, in addition to estimates of corresponding vitamin D exposure.

12. It is important to note that consumption estimates of plant-based drinks are based on cow's milk due to the low number of consumers of plant-based drinks recorded in the NDNS. Additionally, the consumption estimates are based on consumption of cow's milk on its own, in breakfast cereals and in beverages.

13. Estimated minimum and maximum vitamin D levels for margarine and fat spreads were 50 and 75 µg/kg (2,000-3,000 IU), respectively (Sainsbury's, Tesco, 2020). For breakfast cereals, estimated minimum and maximum vitamin D levels were 25 and 84 µg/kg (1,000 and 3,360 IU), respectively (Sainsbury's, 2020). As for dried milk, estimated minimum and maximum vitamin D levels were 1.5 and 46 µg/kg (60 and 1,840 IU), respectively. For evaporated milk, estimated vitamin D levels were 26 and 29 µg/kg. Additionally, plant-based drinks had estimated minimum and maximum vitamin D levels of 7.5 and 18 µg/kg (300-720 IU), respectively. More specifically soya, coconut and almond milk alternatives had vitamin D levels of 7.5 µg/kg (300 IU). Oat milk alternatives had estimated minimum and maximum vitamin D levels of 7.5 and 18 µg/kg (300-720 IU), respectively (Sainsbury's, Tesco, 2020).

14. As noted above, the form of vitamin D that these foods were fortified with was not specified. However, their exposures are compared to the TUL which is protective of both forms of vitamin D (D_2 and D_3).