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

In this guide

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1. Background - Statement on vitamin D Exposure Levels in Formula Fed Infants and Children
2. Introduction - Statement on vitamin D Exposure Levels in Formula Fed Infants and Children
3. Limits for vitamin D content in infant and follow-on formulae
4. Tolerable upper limits for vitamin D:
5. Exposure assessment - Statement on vitamin D Exposure Levels in Formula Fed Infants and Children
6. Risk characterisation - Statement on vitamin D Exposure Levels in Formula Fed Infants and Children
7. Summary & conclusions -Statement on vitamin D Exposure Levels in Formula Fed Infants and Children
8. References - Statement on vitamin D Exposure Levels in Formula Fed Infants and Children
9. Abbreviations - Statement on vitamin D Exposure Levels in Formula Fed Infants and Children
10. Annex A - Statement on vitamin D Exposure Levels in Formula Fed Infants and Children
11. Annex B - Statement on vitamin D Exposure Levels in Formula Fed Infants and Children

Common Infant Formula Products and Vitamin D Supplements Available on the UK Market, and

Occurrence Data Used Regarding Vitamin D in Food (including breast milk)

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 include 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 800g	1.7	68	2.5
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.

Supplement and Age group **4 - 6 months**	**Vitamin D form**	**Recommended intake (as per label) (µg)**
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
Supplement and Age group **6 - 12 months**	**Vitamin D form**	**Recommended intake (as per label) (µg)**
Vitabiotics Wellbaby Multi-Vitamin Liquid 150ml – Boots	D3	10
Baby Ddrops 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
Supplement and Age group **12 - 18 months**	**Vitamin D form**	**Recommended intake (as per label) (µg)**
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

Supplement and Age group 18 - 48 months	Vitamin D form	Recommended intake (as per label) (µg)
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 food (including breast milk) were considered (Table 8 of statement). 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 of statement) and 10 IU/L (equivalent to 0.25 µg vitamin D/ kg breast milk, used for Table 10 of statement), respectively (Dawodu & Tsang, 2012). However, these average concentrations do not include data from UK studies. Other studies of interest are Oberhelman *et al.* (2013) and Hollis *et al.* (2015).

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 of the statement. It is important to note that these estimates are based on all types of cultivated mushrooms, as there are no consumption data on wild mushrooms, and it is uncertain how many, 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 D2 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 of the statement. 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 those for cultivated mushrooms.

Egg yolk

7. Natural sources of vitamin D include egg yolk. Chronic consumption estimates of egg yolk are presented in Table 8 of the statement. 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 of the statement, 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 of the statement. Minimum and maximum reported vitamin D levels of 50 and 160 µg/kg (2,000 and 6,400 IU) (SACN, 2016) were used to estimate exposures.

Animal meat and fat

9. Further sources of vitamin D are animal meat and fat. Exposures from chicken, beef, pork and turkey were considered and are presented in Table 8 of the statement. 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 D3 in animal liver and kidney were derived using chronic consumption data and estimated minimum and maximum vitamin D3 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 of the statement, 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 alternatives to cow's milk had vitamin D levels of 7.5 µg/kg (300 IU). Oat drinks 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 (i.e. D2 and D3) with which these foods were fortified was not specified. However, their exposures are compared to the TUL which is protective of both forms of vitamin D (D2 and D3).