

## **COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT**

### **Discussion paper on the potential effects that excess vitamin D intake may have during preconception, pregnancy and lactation.**

#### **Introduction**

1. The Scientific Advisory Committee on Nutrition (SACN) last considered maternal diet and nutrition in relation to offspring health in its reports on 'The influence of maternal, fetal and child nutrition on the development of chronic disease in later life' (SACN, 2011) and on 'Feeding in the first year of life' (SACN, 2018). In the latter report, the impact of breastfeeding on maternal health was also considered. In 2019, SACN agreed to conduct a risk assessment on nutrition and maternal health focusing on maternal outcomes during pregnancy, childbirth and up to 24 months after delivery; this would include the effects of chemical contaminants and excess nutrients in the diet.

2. SACN agreed that, where appropriate, other expert Committees would be consulted and asked to complete relevant risk assessments e.g. in the area of food safety advice. This subject was initially discussed during horizon scanning at the January 2020 meeting and included background information on a provisional list of chemicals proposed by SACN. SACN noted that the provisional list of chemicals was subject to change following discussion by COT who would be guiding the toxicological risk assessment process; candidate chemicals or chemical classes can be added or removed as the COT considered appropriate. The list was brought back to the COT with additional information in September 2020<sup>1</sup>. Following a discussion at the COT meeting in September 2020, it was agreed that papers on a number of components should be prioritised, including vitamin D. For this paper, the advice of the COT is sought on whether exposure to excess intake of vitamin D would pose a risk to maternal health.

#### **Method of review**

3. The initial bibliographic sources for this discussion paper include the SACN vitamin D and health report<sup>2</sup> and the COT Statement on the adverse effects of high

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<sup>1</sup> COT Contribution to SACN review of nutrition and maternal health: proposed scope of work and timetable. Available at: [https://cot.food.gov.uk/sites/default/files/2020-09/TOX-2020-%2045%20%20Maternal%20diet%20scoping%20paper\\_0.pdf](https://cot.food.gov.uk/sites/default/files/2020-09/TOX-2020-%2045%20%20Maternal%20diet%20scoping%20paper_0.pdf)

<sup>2</sup> <https://www.gov.uk/government/publications/sacn-vitamin-d-and-health-report> -

vitamin D levels<sup>3</sup> which provides most of the background and information on vitamin D function and status. Additional references were identified through an internal FSA literature search tool (Litfetch), which collects literature from the application programming interface (API) of three scientific databases; Scopus, Science Direct and PubMed using single words or combinations of terms described in Annex 3.

## Background

4. Vitamin D refers to two lipid-soluble substances termed *seco*-steroids. One of these (vitamin D<sub>2</sub> or ergocalciferol) is of plant and fungal origin and thus is only accessible to humans via the diet. The other *seco*-steroid (vitamin D<sub>3</sub> or cholecalciferol) is synthesised in mammalian skin by the ultraviolet photolysis of the steroid 7-dehydroxycholesterol (7-DHC) or is obtainable by the consumption of oil rich foods or supplements of animal origin such as cod liver oil. Since vitamin D can be synthesised internally, it is often referred to in the literature as a hormone, rather than a vitamin.

### Vitamin D function and status

5. Vitamin D is important for musculoskeletal health as it regulates calcium and phosphorous metabolism, which is required for normal bone mineralisation, muscle contraction, nerve conduction and general cellular function in all cells in the body. Other possible functions involve its role in the immune system due to the wide distribution of vitamin D receptors on various cells of the immune system. Vitamin D may also play a role in regulation of cell proliferation, cell differentiation and apoptosis as vitamin D-responsive elements are present in a large number of genes associated with the aforementioned cellular processes (COT, 2014).

6. When absorbed or released into systemic circulation, both forms of vitamin D are transported to the liver by Vitamin D Binding Protein (DBP), where they are hydroxylated by cytochrome P450 (CYP) 2R1 to 25-hydroxyvitamin D (25(OH)D), which has a long half-life (about 2-3 weeks) in blood plasma and is widely used as a biomarker for an individual's vitamin D status.

7. 25(OH)D is secreted from the liver into the systemic circulation, where it binds to DBP. When the bound 25(OH)D reaches the kidneys, it is further hydroxylated to the hormonally active product 1,25-dihydroxyvitamin D (1,25(OH)<sub>2</sub>D) by CYP27B1.

8. Vitamin D is lipid soluble, and fat deposits in the body are the major site of vitamin D storage. Excess vitamin D consumption can lead to elevated circulating concentrations and possible toxicity.

9. However, prolonged UVB exposure results in conversion of previtamin D<sub>3</sub> to lumisterol and tachysterol which are biologically inactive (Holick et al., 1981). Cutaneous vitamin D<sub>3</sub> can also isomerise into a variety of photoproducts such as

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<sup>3</sup><https://webarchive.nationalarchives.gov.uk/20200808011447/https://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2014/cot-statement-on-vitamin-d>

suprasterol I, suprasterol II and 5,6 transvitamin D<sub>3</sub> (Webb et al., 1989). “These photoconversions, which are reversible if concentrations of previtamin D<sub>3</sub> fall, prevent accumulation of toxic amounts of vitamin D<sub>3</sub> from cutaneous exposure alone” (SACN, 2016).

10. Serum 25(OH)D concentration is an indicator of an individual’s long-term vitamin D status. Circulating levels of 25(OH)D in the blood are normally in the range of 25-200 nmol/L (COT, 2014) but Hollis (2005) reported circulating levels of 135 to 225 nmol/L in sunny environments where clothing or cultural practices do not prevent sun exposure (COT, 2014). In the UK, evidence of a low vitamin D status has been demonstrated in results of years 9 to 11 of the National Diet and Nutrition Survey (NDNS); 16% of adults aged 19-64 years had a serum 25-(OH)D concentration less than 25 nmol/L between 2016 and 2019 (Bates et al., 2020).

#### Status in pregnancy

11. There is a lack of data on what constitutes a healthy vitamin D status in pregnant women. Functions of vitamin D include regulating the metabolism of calcium and phosphate, which is essential for bone mineralisation (COT, 2014). However, there is no agreement on whether requirements for 25(OH)D are higher during pregnancy compared to non-pregnant adults (Kiely et al., 2020). SACN (2016) did not recommend a separate RNI for pregnant women.

12. Clinical trials with vitamin D supplementation showed the conversion of vitamin D to 25(OH)D appears unchanged (Wagner et al., 2012) or was slightly lower during pregnancy (Kovacs, 2008). This suggest that 25(OH)D levels remain stable during pregnancy (Kovacs, 2008) and the increase in serum 25(OH)D concentration in response to vitamin D supplementation of pregnant and lactating women is similar to that of non-pregnant or non-lactating women (SACN, 2016).

13. However, a number of studies have reported the conversion of 25(OH)D to 1,25(OH)<sub>2</sub>D during the first trimester (12 weeks of pregnancy) as unique; 1,25(OH)<sub>2</sub>D levels double and continue to rise 2 to 3-fold from a non-pregnant adult baseline to over 700 pmol/L (0.7 nmol/L), until delivery without the onset of hypercalciuria or hypercalcemia (Hollis et al., 2017; Heaney et al., 2008; Kovacs, 2008). This increase in 1,25(OH)<sub>2</sub>D observed during pregnancy is not continued throughout lactation (Hollis and Wagner, 2017). Hollis et al. (2011) demonstrated that circulating 25(OH)D levels of approximately 40 ng/ml are required to optimize the production of 1,25(OH)<sub>2</sub>D during human pregnancy via renal and/or placental production. Pregnant women with normal placental function but non-functional renal enzyme 1- $\alpha$ -hydroxylase fail to increase circulating 1,25-dihydroxyvitamin D<sub>3</sub> (1,25(OH)<sub>2</sub>D<sub>3</sub>) during pregnancy (Greer et al., 1984).

14. 25(OH)D is transported via the placenta to the fetus and also converted there to 1,25(OH)<sub>2</sub>D or 24,25-dihydroxyvitamin D (24,25(OH)<sub>2</sub>D) (discussed EFSA, 2018).

15. In lactating women elimination of vitamin D via breast milk accounts for a small percentage of the overall elimination. Vitamin D passes more readily from

circulation into breast milk than 25(OH)D and concentration of vitamin D in breast milk is higher than 25(OH)D and 1,25(OH)<sub>2</sub>D (EFSA, 2016).

### Excess vitamin D – human health studies

16. High oral doses of vitamin D supplements have been shown to have toxic effects, such as hypercalcaemia, dehydration and tissue calcification (Vieth, 2006). Evidence on vitamin D toxicity in humans is based on anecdotal case reports of acute accidental vitamin D<sub>2</sub> or D<sub>3</sub> intoxication resulting in 25(OH)D concentrations of 710-1587 nmol/L and a threshold for toxic symptoms was reported at a concentration of about 750 nmol/L (SACN, 2016). In addition, the previous assessment by the COT reported cases of intoxication associated with serum 25(OH)D levels of as low as 300 nmol/L, and often exceeding 1000 nmol/L (COT, 2014).

17. Hypervitaminosis D (excess vitamin D) can lead to hypercalcaemia<sup>4</sup>, causing deposition of calcium in soft tissues, demineralisation of bones and irreversible renal and cardiovascular toxicity. Hypercalcaemia has been reported at plasma 25(OH)D concentrations above 375-500 nmol/L (SACN, 2016). Hypercalcaemia can also lead to hypercalciuria<sup>5</sup> (EVM, 2003).

18. Vitamin D<sub>2</sub> has been reported to be less potent than vitamin D<sub>3</sub> (Heaney, 2008) with its potency being one third of vitamin D<sub>3</sub> (Armas et al., 2004). Other sources report vitamin D<sub>3</sub> as 87% more potent in raising and maintaining serum 25(OH)D levels (Heaney et al., 2011).

19. Proposed mechanisms of toxicity are based on the over-expression of vitamin D-responsive genes in the nucleus of target cells, induced by 25(OH)D or 1,25(OH)<sub>2</sub>D (Jones, 2008).

### Preconception

20. There is currently no evidence on the effect of excess vitamin D during preconception. A number of studies have examined the potential beneficial effects of vitamin D prior to conception. For example, vitamin D intake of up to 10 µg/d (400 IU) and higher blood vitamin D concentrations (between 75 - 125 nmol/L) during preconception have been associated with increased fecundability (Jukic et al., 2019), reduced risk of pregnancy loss (Mumford et al., 2018 abstract) and reduced risk of gestational diabetes mellitus (Bao et al., 2018). These studies have not been considered further, however, such supplement trials have not resulted in obvious adverse effects being reported, though to what extent such effects would have been ascertained is unknown.

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<sup>4</sup> Hypercalcaemia is generally defined as a total calcium concentration greater than 2.75 mmol/L.

<sup>5</sup> Hypercalciuria is defined as being when urinary excretion of calcium exceeds 250 mg/day in women and 275-300 mg/day in men.

## Pregnancy

21. Data on adverse effects of vitamin D intakes during pregnancy or lactation are lacking (SACN, 2016). No adverse effects were observed in 2 studies (Wagner et al., 2006; Hollis et al., 2011) which supplemented pregnant women with vitamin D doses  $\geq 100 \mu\text{g/d}$  (4000 IU). Additionally, the COT previously noted that “serum calcium has not always been measured in such studies and where it was done, hypercalcaemia was not observed” (COT, 2014). However, there is potential for hypercalcemia to occur during pregnancy in individuals with mutations of genes involved in vitamin D metabolism. A recent case report of a pregnant women with disordered vitamin D metabolism due to a loss of function CYP 24A1 mutations who was supplemented with Vitamin D presented symptomatic hypercalcemia (Macdonald et al., 2020). In an earlier case study, a patient with recurrent hypercalcemia and elevated  $1,25\text{-(OH)}_2\text{D}$  and  $25\text{(OH)D}$  levels during pregnancy showed CYP 24A1 mutations (Shah et al., 2015). In a further case study, the occurrence of hypercalcemia was associated with vitamin D intake at the recommended dose in pregnant women and infants (from two separate families) with loss of function CYP 24A1 mutations) after delivery (Dinour et al., 2015).

22. Excessive vitamin D intake during pregnancy can also result in risk of foetal hypercalcemia (Larquè et al., 2018) and has been evident in neonates born to mothers with an excess maternal vitamin D intake. In a case reported by Reynolds et al. (2017), a female baby was diagnosed with hypercalcemia with  $25\text{(OH)D}$  levels of  $72 \text{ nmol/L}$ , which was at the upper end of the reference range ( $50\text{-}75 \text{ nmol/L}$ ). The baby also had total serum calcium levels of  $3.09 \text{ mmol/L}$ , which was outside the reference range of  $1.9\text{-}2.6 \text{ mmol/L}$ . While the mother, after taking two supplements resulting in a total daily vitamin  $\text{D}_3$  intake of 4000 IU, was reported to have elevated  $25\text{(OH)D}$  levels of  $127 \text{ nmol/L}$ , which was slightly outside the reference range ( $> 125 \text{ nmol/L}$ ). The mother also had total serum calcium levels of  $2.38 \text{ mmol/L}$  which was within the reference range of  $2.1\text{-}2.66 \text{ mmol/L}$ .

23. Other adverse effects of excessive vitamin D intake may include increases in blood pressure as reported in a randomised controlled trial. Healthy pregnant women were administered high doses of vitamin D ( $700 \mu\text{g/week}$ , equivalent to 28,000 IU/week) and showed higher maternal blood pressure than the placebo group at 30-36 weeks of gestation. However, the increases in blood pressure were not clinically classified as hypertension and many of the participants started the trial with low blood pressure. The mean difference in systolic blood pressure was  $0.2 \text{ mmHg}$  (CI =  $-0.1$  to  $0.5$ ) and diastolic blood pressure was  $0.2 \text{ mmHg}$  (CI =  $-0.0$  to  $0.4$ ). However, the mean serum  $25\text{(OH)D}$  levels of participants in this treatment group was  $26.7 \text{ nmol/L}$  (Subramanian et al., 2020), which is considered deficient (SACN, 2016).

## Lactation

24. Although there is very limited evidence for adverse effects relating to vitamin D consumption during lactation (Roth et al., 2018) found that there was a high rate of “possible hypercalciuria” among the women receiving the highest dose of  $700 \mu\text{g/week}$  (28,000 IU/week) in a randomized double-blind, placebo-controlled trial.

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“Possible hypercalciuria” was defined as a single urinary calcium: creatinine ratio of >1, with both calcium and creatinine measured in millimoles (>0.35, with both measured in milligrams). Participants in this category had mean 25(OH)D serum levels of 26.6 nmol/L, which is considered deficient (SACN, 2016).

### **Health based guidance values**

25. In 2016, SACN set a reference nutrient intake (RNI) of 10 µg/day (400 IU/d) for the general population which included pregnant and lactating women and population groups at increased risk of having a serum 25(OH)D concentration <25 nmol/L (SACN, 2016).

26. In 2003, the UK Expert Group on Vitamins and Minerals (EVM) concluded that there was insufficient information to establish a Safe Upper Level (SUL) for vitamin D but noted that for guidance purpose only, intakes of 25 µg/day (1000 IU/d) supplementary vitamin D would not be expected to result in adverse health effects (EVM, 2003).

27. The European Food Safety Authority (EFSA) reviewed vitamin D in 2012 and established a Tolerable Upper Limit (TUL) of 100 µg vitamin D per day for adults and 25, 50 and 100 µg/day vitamin D for infants and children aged up to 12 months, 1-10 years and 11-17 years respectively. EFSA recognized that D<sub>3</sub> may raise 25(OH)D levels more than D<sub>2</sub>, however, as the UL of 100 µg/day is supported by 2 studies both using D<sub>2</sub> and D<sub>3</sub>, EFSA’s TUL is protective of both forms of vitamin D (D<sub>2</sub> and D<sub>3</sub>). The TUL was also not adjusted to take into account pregnancy or lactation as a TUL is intended to apply to all groups of the general population, including individuals, in more sensitive stages of life such as pregnancy. However, the TUL does not cover cases of discrete, identifiable sub-populations who may be especially vulnerable to one or more adverse effects (for example, due to unusual genetic predisposition, certain diseases, or receiving the vitamin under medical supervision) (EFSA, 2006).

28. The COT agreed with EFSA that the UL of 100 µg/d (4000 IU/d) set for adults (≥ 18 years) was appropriate for pregnant and lactating women (SACN, 2016).

### **Vitamin D exposures in maternal health**

#### Sources of vitamin D exposure

29. For most people, UVB radiation is the main source of vitamin D. In the UK, the main dietary sources of vitamin D are foods of animal origin, fortified foods and supplements (SACN, 2016).

#### Food

30. There are limited sources of vitamin D<sub>2</sub> from food. Wild mushrooms are a rich natural source, containing 13-30µg (520-1200 IU) per 100g fresh weight (Mattila et

al., 1994). Cultivated mushrooms do not contain high amounts of vitamin D<sub>2</sub> since they are grown in the dark, but UVB treated vitamin D<sub>2</sub> enhanced mushrooms are now commercially available.

31. Rich sources of vitamin D<sub>3</sub> include egg yolk (12.6 µg/504 IU per 100g) and oily fish (5-16 µg/200-640 IU per 100g) such as salmon, mackerel, herring and sardines. Animal products such as meat, fat, liver and kidney also contain vitamin D<sub>3</sub> (0.1-1.5 µg/4-60 IU per 100g). Vitamin D<sub>3</sub> in addition to 7-DHC has also been identified in the leaves of plant species belonging to the Solanaceae family (which includes vegetables such as potato, tomato and pepper). Wide variations have been reported in how much vitamin D<sub>3</sub> and 7-DHC these plants contain. Vitamin D<sub>3</sub> has been reported to be present between <0.1-0.28 µg/g dry weight and 0.1- 42 µg/g fresh weight, whereas 7-DHC has been reported to be present between 2 -1.3 µg/g dry weight and 5-58µg/g fresh weight. However, it is unknown if the edible portions of plants in this family also contain vitamin D<sub>3</sub> (SACN, 2016).

32. In the UK, foods such as fat spreads, breakfast cereals, dried and evaporated milk can also be fortified with vitamin D<sub>3</sub> or D<sub>2</sub> on a voluntary basis (SACN, 2016). The following data on fortification levels of vitamin D were collected from UK supermarket websites and are presented in Table A2 of Annex 2. However, the nutritional information provided by the retailer did not specify if foods were fortified with vitamin D<sub>2</sub>, D<sub>3</sub> or both.

33. The level of fortification of vitamin D in 20 samples ranged between 5-7.5 µg/100g of margarines and fat spreads (Sainsbury's, Tesco, 2020). As for breakfast cereals, data collected from UK supermarket websites showed the level of fortification of vitamin D in 36 samples to range between 2.5-8.4µg per 100g of breakfast cereals (Sainsbury's, 2020).

#### Cow's milk and milk products

34. As for cow's milk, "in the UK, cows' milk is generally not a good source of vitamin D because it is not fortified, as it is in some other countries" (NHS, 2020). However, dried and evaporated milks are fortified with vitamin D on a voluntary basis (SACN, 2016). Data collected from UK supermarket websites showed the level of fortification of vitamin D to be between 0.15-4.6 µg per 100 g of in 3 samples dried milk, and 2.6-2.9 µg per 100g in 2 samples of evaporated milk (Sainsbury's Tesco, 2020).

#### Supplements

35. Dietary vitamin D supplements contain either vitamin D<sub>2</sub> or D<sub>3</sub>, they are synthesised commercially by UVB irradiation of 7-DHC (from sheep wool) and ergosterol (from fungi) respectively (Bikle, 2009). Vitamin D supplements can also be administered by intramuscular injection.

36. Table A1 of Annex 1 provides a list of supplements taken from the OTC directory (PAGB, OTC, 2002) and other sources (Vitabiotics, 2020; iHerb, 2020) that contain vitamin D. The concentration of vitamin D in these supplements range from 4 -180 µg/day.

37. From late March/early April to the end of September, most people should be able to get all the vitamin D they need from sunlight on their skin and a balanced diet. During the autumn and winter, all adults (including pregnant and breastfeeding women) and children over four years old are advised to consider taking a daily vitamin D supplement (10 micrograms/400 IU) to protect bone and muscle health. Groups who are at risk of not obtaining enough vitamin D from sunlight exposure are advised to take a vitamin D supplement all year round. These groups include people with dark skin (such as those with African, African-Caribbean or South Asian backgrounds), those who spend most of their time indoors (for example, because of frailty or they are living in a care home) and those who cover most of their skin when outdoors.

### Exposure assessment

38. The following exposure assessments are based on consumption data from the NDNS (Bates et al., 2014, 2016, 2018), it is important to note that the NDNS does not provide data for pregnant or lactating women. Therefore, data presented below is based on women of childbearing age (16-49 years) and consumption data may not entirely be representative of the maternal diet.

Exposure estimates from foods with naturally occurring vitamin D<sub>2</sub>.

Mushrooms:

39. As per paragraph 30, wild mushrooms are a natural source of vitamin D<sub>2</sub>. A search within the recipes database of the NDNS (Bates et al., 2014, 2016, 2018) was conducted to retrieve mushrooms and recipes containing mushrooms which had been recorded in the survey.

40. The chronic consumption estimates of mushrooms are presented in Table 1. It is important to consider that these estimates are based on all mushrooms, as there is negligible consumption data on wild mushrooms in the NDNS (Bates et al., 2014, 2016).

Table 1. Estimated chronic consumption of mushrooms in women aged 16-49 years (Bates et al., 2014, 2016; 2018)\*\*

| Number of consumers | (g/person/day)<br>* |                               | g/kg<br>bw/day* |                               | Respondents in population |
|---------------------|---------------------|-------------------------------|-----------------|-------------------------------|---------------------------|
|                     | Mean                | 97.5 <sup>th</sup> percentile | Mean            | 97.5 <sup>th</sup> percentile |                           |
| 871                 | 11                  | 49                            | 0.16            | 0.70                          | 1874                      |

\* Rounded to 2 s.f

\*\*Based on all mushrooms in the NDNS database not just wild mushrooms



41. Exposure estimates of vitamin D<sub>2</sub> in mushrooms were calculated using chronic consumption data from Table 1 and, the minimum and maximum estimated vitamin D<sub>2</sub> levels for wild mushrooms which are 130 and 300 µg/kg respectively (SACN, 2016), these are given in Table 2.

Table 2. Estimated chronic exposure of vitamin D<sub>2</sub> in mushrooms in women aged 16-49 years (Bates et al., 2014, 2016; 2018)\*\*

| Vitamin D concentration (µg/kg) | (µg/person/day)* |                               | µg/kg bw/day* |                               |
|---------------------------------|------------------|-------------------------------|---------------|-------------------------------|
|                                 | Mean             | 97.5 <sup>th</sup> percentile | Mean          | 97.5 <sup>th</sup> percentile |
| Minimum:130                     | 1.5              | 6.4                           | 0.021         | 0.091                         |
| Maximum: 300                    | 3.4              | 15                            | 0.049         | 0.21                          |

\* Rounded to 2 s.f

\*\*Based on all mushrooms in the NDNS database not just wild mushrooms

Exposure estimates from foods with naturally occurring vitamin D<sub>3</sub>.

Egg yolk:

42. Natural sources of Vitamin D<sub>3</sub> include egg yolk, chronic consumption estimates of egg yolk are presented in Table 3. It is important to note that whole egg consumption from the NDNS database was considered in order to ensure that all egg yolk consumers were included. 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, 2012). The factor of 29% was then applied to whole eggs foods to give estimates for consumption specifically of egg yolks, and foods containing solely egg whites were removed from the assessment.

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Table 3. Estimated chronic consumption data of egg yolk in women aged 16-49 years (Bates et al., 2014, 2016; 2018)\*\*

| Number of consumers | (g/person/day)* |                               | g/kg bw/day* |                               | Respondents in population |
|---------------------|-----------------|-------------------------------|--------------|-------------------------------|---------------------------|
|                     | Mean            | 97.5 <sup>th</sup> percentile | Mean         | 97.5 <sup>th</sup> percentile |                           |
| 903                 | 8.5             | 25                            | 0.13         | 0.38                          | 1874                      |

\* Rounded to 2 s.f

\*\*Assumption: Average egg contains 29% egg yolk

43. Exposure estimates of vitamin D<sub>3</sub> in egg yolk using chronic consumption data from Table 3 and estimated vitamin D<sub>3</sub> levels of 126 µg/kg (SACN, 2016) are presented in Table 4.

Table 4. Estimated chronic exposure of vitamin D<sub>3</sub> in egg yolk in women aged 16-49 years (Bates et al., 2014, 2016; 2018)\*\*

| Vitamin D concentration (µg/kg) | (µg/person/day)* |                               | µg/kg bw/day* |                               |
|---------------------------------|------------------|-------------------------------|---------------|-------------------------------|
|                                 | Mean             | 97.5 <sup>th</sup> percentile | Mean          | 97.5 <sup>th</sup> percentile |
| 126                             | 1.1              | 3.2                           | 0.016         | 0.048                         |

\* Rounded to 2 s.f

\*\*Assumption: Average egg contains 29% egg yolk

Oily fish:

44. Additional sources of vitamin D<sub>3</sub> are oily fish such as salmon, mackerel, herring and sardines, for which chronic consumption data is presented in Table 5.

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Table 5. Estimated chronic consumption data of oily fish in women aged 16-49 years (Bates et al., 2014, 2016; 2018)\*\*

| Number of consumers | (g/person/day)* |                               | g/kg bw/day* |                               | Respondents in population |
|---------------------|-----------------|-------------------------------|--------------|-------------------------------|---------------------------|
|                     | Mean            | 97.5 <sup>th</sup> percentile | Mean         | 97.5 <sup>th</sup> percentile |                           |
| 311                 | 25              | 70                            | 0.38         | 1.3                           | 1874                      |

\* Rounded to 2 s.f

\*\*Based on salmon, mackerel, herring and sardines

45. Exposure estimates of vitamin D<sub>3</sub> in oil fish using chronic consumption data from Table 5 and minimum and maximum estimated vitamin D<sub>3</sub> levels of 50 and 160 µg/kg (SACN, 2016) respectively are presented in Table 6.

Table 6. Estimated chronic exposure of vitamin D<sub>3</sub> in oily fish (salmon, mackerel, herring and sardines) in women aged 16-49 years (Bates et al., 2014, 2016; 2018)\*\*

| Vitamin D concentration (µg/kg) | (µg/person/day)* |                               | µg/kg bw/day* |                               |
|---------------------------------|------------------|-------------------------------|---------------|-------------------------------|
|                                 | Mean             | 97.5 <sup>th</sup> percentile | Mean          | 97.5 <sup>th</sup> percentile |
| Minimum:50                      | 1.3              | 3.5                           | 0.019         | 0.066                         |
| Maximum: 160                    | 4.0              | 11                            | 0.061         | 0.21                          |

\* Rounded to 2 s.f

\*\* Based on salmon, mackerel, herring and sardines

Animal meat and fat:

46. Further sources of vitamin D<sub>3</sub> are animal meat and animal fat. Consumption estimates of various types of animal meat and fat (chicken, beef, pork and turkey) are presented in Tables 7-10. Consumption of animal meat and animal fat were considered together as animal fat is likely to be consumed alongside animal meat. Additionally, the number of consumers of animal fat alone would be very low.

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Table 7. Estimated chronic consumption of chicken and chicken fat in women aged 16-49 years (Bates et al., 2014, 2016; 2018)\*\*

| Number of consumers | (g/person/day)* |                               | g/kg bw/day* |                               | Respondents in population |
|---------------------|-----------------|-------------------------------|--------------|-------------------------------|---------------------------|
|                     | Mean            | 97.5 <sup>th</sup> percentile | Mean         | 97.5 <sup>th</sup> percentile |                           |
| 1076                | 34              | 98                            | 0.50         | 1.4                           | 1874                      |

\* Rounded to 2 s.f

\*\* Chicken and chicken fat have been considered together.

Table 8. Estimated chronic consumption of beef and beef fat in women aged 16-49 years (Bates et al., 2014, 2016; 2018)\*\*

| Number of consumers | (g/person/day)* |                               | g/kg bw/day* |                               | Respondents in population |
|---------------------|-----------------|-------------------------------|--------------|-------------------------------|---------------------------|
|                     | Mean            | 97.5 <sup>th</sup> percentile | Mean         | 97.5 <sup>th</sup> percentile |                           |
| 1189                | 26              | 82                            | 0.38         | 1.2                           | 1874                      |

\* Rounded to 2 s.f

\*\* Beef and beef fat have been considered together.

Table 9. Estimated chronic consumption of pork and pork fat in women aged 16-49 years (Bates et al., 2014, 2016; 2018)\*\*

| Number of consumers | (g/person/day)* |                               | g/kg bw/day* |                               | Respondents in population |
|---------------------|-----------------|-------------------------------|--------------|-------------------------------|---------------------------|
|                     | Mean            | 97.5 <sup>th</sup> percentile | Mean         | 97.5 <sup>th</sup> percentile |                           |
| 1110                | 23              | 80                            | 0.33         | 1.3                           | 1874                      |

\* Rounded to 2 s.f

\*\* Pork and pork fat have been considered together.

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Table 10. Estimated chronic consumption of turkey and turkey fat in women aged 16-49 years (Bates et al. (Bates et al., 2014, 2016; 2018)\*\*

| Number of consumers | (g/person/day)* |                               | g/kg bw/day* |                               | Respondents in population |
|---------------------|-----------------|-------------------------------|--------------|-------------------------------|---------------------------|
|                     | Mean            | 97.5 <sup>th</sup> percentile | Mean         | 97.5 <sup>th</sup> percentile |                           |
| 170                 | 26              | 93                            | 0.39         | 1.4                           | 1874                      |

\* Rounded to 2 s.f

\*\* Turkey and turkey fat have been considered together.

47. Exposure estimates of vitamin D<sub>3</sub> in animal meat and animal fat using chronic consumption data from Table 7-10 and minimum and maximum estimated vitamin D<sub>3</sub> levels of 1 and 15 µg/kg respectively (SACN, 2016) are presented in Table 11-14.

Table 11. Estimated chronic exposure of vitamin D<sub>3</sub> in chicken and chicken fat in women aged 16-49 years (Bates et al., 2014, 2016, 2018)\*\*

| Vitamin D concentration (µg/kg) | (µg/person/day)* |                               | µg/kg bw/day* |                               |
|---------------------------------|------------------|-------------------------------|---------------|-------------------------------|
|                                 | Mean             | 97.5 <sup>th</sup> percentile | Mean          | 97.5 <sup>th</sup> percentile |
| Minimum:1                       | 0.034            | 0.096                         | 0.00050       | 0.0014                        |
| Maximum: 15                     | 0.51             | 1.5                           | 0.0074        | 0.021                         |

\* Rounded to 2 s.f

\*\* Chicken and chicken fat have been considered together.

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Table 12: Estimated chronic exposure of vitamin D<sub>3</sub> in pork and pork fat in women aged 16-49 years (Bates et al., 2014, 2016, 2018)\*\*

|  | <b>(µg/person/day)*</b> |                                     | <b>µg/kg bw/day*</b> |                                     |
|--|-------------------------|-------------------------------------|----------------------|-------------------------------------|
|  | <b>Mean</b>             | <b>97.5<sup>th</sup> percentile</b> | <b>Mean</b>          | <b>97.5<sup>th</sup> percentile</b> |
| <b>Vitamin D concentration (µg/kg)</b> |                         |                                     |                      |                                     |
| Minimum:1                              | 0.023                   | 0.080                               | 0.00033              | 0.0013                              |
| Maximum: 15                            | 0.34                    | 1.2                                 | 0.0049               | 0.019                               |

\* Rounded to 2 s.f

\*\* Pork and pork fat have been considered together.

Table 13: Estimated chronic exposure of vitamin D<sub>3</sub> in beef and beef fat in women aged 16-49 years (Bates et al., 2014, 2016, 2018)\*\*

|  | <b>(µg/person/day)*</b> |                                     | <b>µg/kg bw/day*</b> |                                     |
|--|-------------------------|-------------------------------------|----------------------|-------------------------------------|
|  | <b>Mean</b>             | <b>97.5<sup>th</sup> percentile</b> | <b>Mean</b>          | <b>97.5<sup>th</sup> percentile</b> |
| <b>Vitamin D concentration (µg/kg)</b> |                         |                                     |                      |                                     |
| Minimum:1                              | 0.026                   | 0.082                               | 0.00038              | 0.0012                              |
| Maximum: 15                            | 0.39                    | 1.2                                 | 0.0056               | 0.018                               |

\* Rounded to 2 s.f

\*\* Beef and beef fat have been considered together.

Table 14: Estimated chronic exposure of vitamin D<sub>3</sub> in turkey and turkey fat in women aged 16-49 years (Bates et al., 2014, 2016, 2018)\*\*

|  | <b>(µg/person/day)*</b> |                                     | <b>µg/kg bw/day*</b> |                                     |
|--|-------------------------|-------------------------------------|----------------------|-------------------------------------|
|  | <b>Mean</b>             | <b>97.5<sup>th</sup> percentile</b> | <b>Mean</b>          | <b>97.5<sup>th</sup> percentile</b> |
| <b>Vitamin D concentration (µg/kg)</b> |                         |                                     |                      |                                     |
| Minimum:1                              | 0.026                   | 0.093                               | 0.00039              | 0.0014                              |
| Maximum: 15                            | 0.39                    | 1.4                                 | 0.0059               | 0.022                               |

\* Rounded to 2 s.f

\*\* Turkey and turkey fat have been considered together.

Animal offal:

48. Other sources of vitamin D<sub>3</sub> is animal liver and kidney. Consumption estimates of animal liver and kidney are based on overall animal offal consumption and are presented in Table 15. Consumption was based on all animal offal as liver and kidney were given as examples of offal that contain vitamin D<sub>3</sub> in the 2016 SACN report and other types of offal were not specified (SACN, 2016).

Table 15. Estimated chronic consumption of animal liver and kidney in women aged 16-49 years (Bates et al., 2014, 2016; 2018)\*\*

| Number of consumers | (g/person/day)* |                               | g/kg bw/day* |                               | Respondents in population |
|---------------------|-----------------|-------------------------------|--------------|-------------------------------|---------------------------|
|                     | Mean            | 97.5 <sup>th</sup> percentile | Mean         | 97.5 <sup>th</sup> percentile |                           |
| 107                 | 13              | 37                            | 0.19         | 0.56                          | 1874                      |

\*Rounded to 2 s.f

\*\* Based on all animal offal

49. Exposure estimates of vitamin D<sub>3</sub> in animal liver and kidney using chronic consumption data from Table 15 and minimum and maximum estimated vitamin D<sub>3</sub> levels of 1 and 15 µg/kg respectively (SACN, 2016) are presented in Table 16.

Table 16. Estimated chronic exposure of vitamin D<sub>3</sub> in animal liver and kidney in women aged 16-49 years (Bates et al., 2014, 2016, 2018)\*\*

| Vitamin D concentration (µg/kg) | (µg/person/day)* |                               | µg/kg bw/day* |                               |
|---------------------------------|------------------|-------------------------------|---------------|-------------------------------|
|                                 | Mean             | 97.5 <sup>th</sup> percentile | Mean          | 97.5 <sup>th</sup> percentile |
| Minimum:1                       | 0.013            | 0.037                         | 0.00019       | 0.00056                       |
| Maximum: 15                     | 0.19             | 0.56                          | 0.0028        | 0.0084                        |

\* Rounded to 2 s.f

\*\*Based on all animal offal

Exposure estimates from food voluntarily fortified with Vitamin D

50. As previously mentioned, the following foods are voluntarily fortified with vitamin D: margarines and fat spreads, breakfast cereals, dried and evaporated milk. Consumption estimates of the aforementioned food products are presented in Table 17.

Table 17. Estimated chronic consumption of voluntarily fortified foods in women aged 16-49 years (Bates et al., 2014, 2016; 2018)

|                                  | (g/person/day)<br>* |                                  | g/kg<br>bw/day* |                                  | Respondents<br>in population |
|----------------------------------|---------------------|----------------------------------|-----------------|----------------------------------|------------------------------|
| Number of<br>consumers           | Mean                | 97.5 <sup>th</sup><br>percentile | Mean            | 97.5 <sup>th</sup><br>percentile |                              |
| <b>Margarine and fat spreads</b> |                     |                                  |                 |                                  | 1874                         |
| 1096                             | 9.0                 | 28                               | 0.13            | 0.42                             |                              |
| <b>Breakfast cereals</b>         |                     |                                  |                 |                                  |                              |
| 923                              | 27                  | 120                              | 0.40            | 1.8                              |                              |
| <b>Dried milk</b>                |                     |                                  |                 |                                  |                              |
| 1221                             | 2.9                 | 11                               | 0.043           | 0.18                             |                              |
| <b>Evaporated milk</b>           |                     |                                  |                 |                                  |                              |
| 16                               | 8.8                 | 33                               | 0.12            | 0.47                             |                              |

\*Rounded to 2 s.f

51. Exposure estimates of vitamin D in fortified foods using chronic consumption data from Table 17 and various minimum and maximum estimated vitamin D levels are presented in Table 18.

52. Minimum and maximum estimated vitamin D levels for margarine and fat spreads were 50 and 75 µg/kg (Sainsbury's, Tesco, 2020) respectively. For breakfast cereals minimum and maximum estimated vitamin D levels were 25 and 84 µg/kg (Sainsbury's 2020). As for dried milk minimum and maximum estimated vitamin D levels were 1.5 and 46 µg/kg respectively, and for evaporated milk estimated vitamin D levels were 26 and 29 µg/kg (Sainsbury's, Tesco, 2020).



53. As discussed in paragraph 32, the form of vitamin D that these foods were fortified with were not specified. However, their exposures will be compared to the TUL of 100 µg/day which is protective of both forms of vitamin D (D<sub>2</sub> and D<sub>3</sub>).

Table 18. Estimated chronic exposure of vitamin D in fortified foods (margarine and fat spreads, breakfast cereals and dried and evaporated milk) in women aged 16-49 years (Bates et al., 2014, 2016, 2018)\*\*

| Vitamin D concentration (µg/kg)  | (µg/person/day)* |                               | µg/kg bw/day* |                               |
|----------------------------------|------------------|-------------------------------|---------------|-------------------------------|
|                                  | Mean             | 97.5 <sup>th</sup> percentile | Mean          | 97.5 <sup>th</sup> percentile |
| <b>Margarine and fat spreads</b> |                  |                               |               |                               |
| Minimum: 50                      | 0.45             | 1.4                           | 0.0066        | 0.021                         |
| Maximum: 75                      | 0.67             | 2.1                           | 0.0099        | 0.031                         |
| <b>Breakfast cereals</b>         |                  |                               |               |                               |
| Minimum: 25                      | 0.66             | 3.0                           | 0.010         | 0.044                         |
| Maximum: 84                      | 2.2              | 10                            | 0.033         | 0.15                          |
| <b>Dried milk</b>                |                  |                               |               |                               |
| Minimum: 1.5                     | 0.0044           | 0.017                         | 0.000065      | 0.00027                       |
| Maximum: 46                      | 0.13             | 0.51                          | 0.0020        | 0.0082                        |
| <b>Evaporated milk</b>           |                  |                               |               |                               |
| Minimum: 26                      | 0.23             | 0.87                          | 0.0032        | 0.012                         |
| Maximum: 29                      | 0.26             | 0.97                          | 0.0036        | 0.014                         |

\* Rounded to 2 s.f

\*\* Estimated vitamin D levels were based on the following samples numbers: Breakfast cereal n = 36; Dried milk n=3; Evaporated milk n=2; Margarine and fat spreads = 20.

Exposure estimates from supplements only

54. The most recent NDNS report has showed that between 2016 and 2019 20% of female respondents aged 19-64 years were vitamin D supplement takers (Bates et al., 2020).

55. Supplements available in the UK that contain vitamin D are listed in table A1 of the Annex. Supplements aimed at non-pregnant adults contained vitamin D in concentrations ranging from 5 to 180 µg/day. The supplements containing vitamin D that are aimed at pregnant and breast-feeding women contain no more than 10 µg/day of vitamin D. As for women attempting conception supplements contain no more than 20 µg/day of vitamin D.

56. Mean and 97.5<sup>th</sup> percentile values of all vitamin D containing supplements presented in Table A1 of Annex 1 are presented in Table 19. It is important to consider that the calculated mean and 97.5<sup>th</sup> percentile values are based on a limited number of vitamin D containing supplements and not all that are currently made accessible to the UK.

Table 19. Mean and 97.5<sup>th</sup> percentile concentrations of vitamin D containing supplements presented in Table A1 of Annex 1.\*\*

| Vitamin D concentration | (µg/person/day)* |                               | µg/kg bw/day* |                               |
|-------------------------|------------------|-------------------------------|---------------|-------------------------------|
|                         | Mean             | 97.5 <sup>th</sup> percentile | Mean          | 97.5 <sup>th</sup> percentile |
|                         | 17               | 162                           | 0.22          | 2.08                          |

\* Rounded to 2 s.f

\*\* Mean and 97.5<sup>th</sup> percentile estimates are based on 48 vitamin D containing supplements

Estimated total vitamin D exposure from food sources only (excluding supplements)

57. In the most recent NDNS survey, female respondents aged 19-64 years had mean and 97.5<sup>th</sup> percentile vitamin D intake of 2.6 and 7.7 µg/day respectively from all food sources (excluding dietary supplements) (Bates et al., 2020).

58. More specific estimated total exposure to vitamin D from food sources in women aged 16-49 years only are presented in Table 20 below. This data has been summed from the exposure estimates in tables 2, 4, 6, 11-14, 16 and 18. Exposure data from food sources containing both forms of vitamin D (D<sub>2</sub> and D<sub>3</sub>) were summed together as their exposures will be compared to the TUL of 100 µg/day which is protective of both forms of vitamin D (D<sub>2</sub> and D<sub>3</sub>).

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Table 20. Estimated total vitamin D exposure from food sources only (excluding supplements) in women aged 16-49 years.

| Total vitamin D intake - (food sources) | (µg/person/day)* |                               | µg/kg bw/day* |                               |
|---|------------------|-------------------------------|---------------|-------------------------------|
|   | Mean             | 97.5 <sup>th</sup> percentile | Mean          | 97.5 <sup>th</sup> percentile |
| Minimum                                 | 5.4              | 19                            | 0.078         | 0.29                          |
| Maximum                                 | 14               | 49                            | 0.20          | 0.76                          |

\* Rounded to 2 s.f

59. Minimum vitamin D intake from food sources only amongst women aged 16-49 years were 5.4 µg/day and 19 µg/day in mean and 97.5<sup>th</sup> percentile groups respectively. Alternatively, maximum vitamin D intake from food sources only were 14 and 49 µg/day in mean and 97.5<sup>th</sup> percentile groups respectively.

Estimated total vitamin D exposure from all dietary sources (including supplements):

60. In the most recent NDNS survey, female respondents aged 19-64 years had mean and 97.5<sup>th</sup> percentile vitamin D intake of 5.5 and 26.6 µg/day respectively from all food sources (including dietary supplements) (Bates et al., 2020).

61. More specific estimated total exposure to vitamin D from all dietary sources (including supplements) in women aged 16-49 years are presented in Table 21 below. The exposure data from food sources in tables 2, 4, 6, 11-14, 16 and 18 were summed with exposure data from dietary supplements (Table 19). Exposure data from food sources and supplements containing both forms of vitamin D (D<sub>2</sub> and D<sub>3</sub>) were summed together as their exposures will be compared to the TUL of 100 µg/day is protective of both forms of vitamin D (D<sub>2</sub> and D<sub>3</sub>).

Table 21. Estimated total vitamin D exposure from all dietary sources (including supplements) in women aged 16-49 years.

| Total vitamin D intake - (all sources inc. supplements) | (µg/person/day)* |                               | µg/kg bw/day* |                               |
|---|------------------|-------------------------------|---------------|-------------------------------|
|   | Mean             | 97.5 <sup>th</sup> percentile | Mean          | 97.5 <sup>th</sup> percentile |
| Minimum   | 22               | 180                           | 0.30          | 2.4                           |
| Maximum   | 31               | 210                           | 0.42          | 2.8                           |

\* Rounded to 2 s.f

62. Minimum total vitamin D intake from all dietary sources (including vitamin D) amongst women aged 16-49 years were 22 and 180 µg/day in mean and 97.5<sup>th</sup> percentile groups respectively. Alternatively, maximum total vitamin D intake from all food sources were 31 and 210 µg/day in mean and 97.5<sup>th</sup> percentile groups respectively.

### Risk characterisation

63. The total vitamin D intake from all food sources (excluding supplements) amongst females aged 19-64 years in the most recent NDNS survey, were 2.6 and 7.7 µg/day for mean and 97.5<sup>th</sup> percentile values respectively (Bates et al., 2020). Both mean and 97.5<sup>th</sup> percentile values were well below the TUL of 100 µg/day (EFSA, 2012), and therefore do not indicate toxicological concern. However, these intake estimates include women outside of child-bearing age.

64. All mean and 97.5<sup>th</sup> percentile exposures from food sources (excluding supplements) for women of child-bearing age (i.e. 16-49 years) are within the TUL of 100 µg/day (EFSA, 2012) and are therefore not of toxicological concern.

65. Majority of the vitamin D containing supplements aimed at regular adults are available in concentrations ranging from 4 to 180 µg/day, most of which do not exceed the TUL of 100 µg/d. However, the highest dosed vitamin D containing supplement; Zahler, Vitamin D3, (Annex 1) exceeded the TUL by approximately 2-fold. Consumption of this supplement and supplements containing vitamin D greater than 100 µg/day may increase risk of hypercalcemia and hypercalciuria in women attempting conception, pregnant and lactating women. Despite the possible exceedances with some supplements it is important to note that occasional or short-term consumption of “doses of 7500 µg at intervals of 3 months or longer would not be expected to cause adverse effects in adults” (COT, 2014), but sustained consumption could be of toxicological concern.

66. Supplements listed in Table A1 of Annex 1 that are aimed at pregnant and breast-feeding women do not exceed the TUL for vitamin D of 100µg/day (EFSA, 2012), and therefore exposure to vitamin D in these supplements alone are unlikely to be of toxicological concern to women attempting conception, pregnant and breast-feeding women.

67. The vitamin D intake from all dietary sources (including supplements) amongst females aged 19-64 years in the most recent NDNS survey were 5.5 and 26.6 µg/day for mean and 97.5<sup>th</sup> percentile groups respectively (Bates et al., 2020) which is below the TUL of 100 µg/day (EFSA, 2012). However, these intake estimates include women outside of child-bearing age.

68. When considering estimates from all dietary sources (including dietary supplements) for women of child-bearing age (i.e. 16-49 years) mean total intakes were within the TUL of 100 µg/day. Estimated intakes at the 97.5<sup>th</sup> percentiles exceeded the TUL approximately 2-fold and a risk of hypercalcemia and hypercalciuria in women attempting conception, pregnant and lactating women cannot be excluded.

## Conclusions

69. Women attempting conception, pregnant and lactating women who do not take supplements, and whose only exposure to vitamin D is from food sources only, are unlikely to be at risk of adverse health effects such as hypercalcemia and hypercalciuria, as all exposure estimates for women in this category are below the TUL of 100 µg/day. However, effects to health cannot be excluded, especially in sensitive individuals who may have loss of function mutations.

70. When considering estimates from all dietary sources, including dietary supplements, for woman of childbearing age, mean total intakes were within the TUL of 100 µg/day. Estimated intakes at the 97.5<sup>th</sup> percentiles exceeded the TUL approximately 2-fold and a risk of hypercalcemia and hypercalciuria in women attempting conception, pregnant and lactating women cannot be excluded.

71. Overall, current exposures to vitamin D from foods and supplements are unlikely to be of toxicological concern to the majority of women attempting conception, pregnant or lactating women.

## Questions for the committee

- a) Do Members consider that current intakes of vitamin D pose a risk to women of childbearing age, pregnant women or lactating mothers?
- b) Do the Committee have any further comments?

## Secretariat

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**February 2021**

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## Abbreviations

|                          |  |
|--------------------------|--|
| 1,25(OH) <sub>2</sub> D  | 1,25-dihydroxyvitamin D                    |
| 7-DHC                    | 7-dehydroxycholesterol                     |
| 24,25(OH) <sub>2</sub> D | 24,25-dihydroxyvitamin D                   |
| 25(OH)D                  | 25-hydroxyvitamin D                        |
| COT                      | The Committee on Toxicity                  |
| CYP 2R1                  | Cytochrome P450 2R1                        |
| DBP                      | Vitamin D Binding Protein                  |
| DH                       | Department of Health                       |
| EFSA                     | The European Food Safety Authority         |
| EVM                      | Expert group on Vitamins and Minerals      |
| HBGV                     | Health Based Guidance Value                |
| IU                       | International Units                        |
| Kg                       | Kilograms                                  |
| NDNS                     | National Diet and Nutrition Survey         |
| n                        | Number of samples                          |
| NHS                      | National Health Service                    |
| RNI                      | Reference Nutrient Intake                  |
| SACN                     | Scientific Advisory Committee on Nutrition |
| TUL                      | Tolerable Upper Limit                      |
| µg                       | Micrograms                                 |
| UK                       | United Kingdom                             |
| UVB                      | Ultraviolet B                              |

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Table A1: List of supplements that contain vitamin D, taken from the OTC online directory and other sources (OTC, 2020; Vitabiotics, 2020; iHerb, 2020)

| Supplement Name   | Dosage                         | Total Concentration (µg) |
|---|--------------------------------|--------------------------|
| <b>Supplements aimed at adults</b>  |                                |                          |
| Seven Seas Omega-3 Fish Oil plus Cod Liver Oil One-A-Day                            | 1 capsule/day                  | 4                        |
| Bassetts Vitamins Adults Multivitamins Raspberry & Pomegranate                      | 1 pastille/day                 | 5                        |
| Centrum Advance   | 1 tablet/day                   | 5                        |
| Centrum Performance   | 1 tablet/day                   | 5                        |
| Haliborange Multivitamins Calcium & Iron Tablet                                     | 1-2 tablets                    | 5                        |
| Haliborange Vitamins A, C & D Orange Chewable Tablets                               | 1 tablet                       | 5                        |
| Minavex Multivitamin Liquid – Orange Flavour *CHECK*                                | 5ml/day                        | 5                        |
| Pharmaton Active Life Caplets   | 1 tablet/day                   | 5                        |
| Sanatogen A-Z Complete  | 1 tablet/day                   | 5                        |
| Seven Seas Complete Multivitamins Adult Tablets                                     | 1 tablet/day                   | 5                        |
| Seven Seas Jointcare Supplex & Turmeric   | 1 capsule/day<br>1 tablet/day  | 5                        |
| Seven Seas Omega-3 Fish Oil plus Cod Liver Oil + Magnesium                          | 1 capsules/day<br>1 tablet/day | 5                        |
| Seven Seas Omega-3 Fish Oil plus Cod Liver Oil + Turmeric                           | 1 capsule<br>1 tablet/day      | 5                        |
| Seven Seas Omega-3 Fish Oil plus Cod Liver Oil Gelatine Free High Strength Capsules | 1 capsule/day                  | 5                        |
| Seven Seas Omega-3 Fish Oil plus Cod Liver Oil Maximum Strength Capsules            | 1 capsule/day                  | 5                        |
| Seven Seas Omega-3 Fish Oil plus Cod Liver Oil Maximum Strength Liquid              | 2 5 ml<br>teaspoon/day         | 5                        |
| Seven Seas Omega-3 Fish Oil plus Cod Liver Oil Orange Flavour Liquid                | 2 5ml<br>teaspoon/day          | 5                        |
| Seven Seas Omega-3 Fish Oil plus Cod Liver Oil plus Calcium                         | 1 capsule/day                  | 5                        |
| Seven Seas Omega-3 Fish Oil plus Cod Liver Oil plus Evening Primrose Oil Capsules   | 1 capsule/day                  | 5                        |
| Seven Seas Omega-3 Fish Oil plus Cod Liver Oil plus Multivitamins                   | 1 capsule/day                  | 5                        |
| Seven Seas Perfect7 Woman Plus  | 1 tablet<br>1 capsule/day      | 5                        |

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|  |                           |         |
|--|---------------------------|---------|
| Emergen-C  | 1 sachet                  | 10      |
| Forceval capsules*   | 1 capsule/day             | 10      |
| Forceval Soluble*  | 1 tablet                  | 10      |
| Multibionta Vitality Tailored Multivitamin with Minerals & Biotic Cultures | 1 tablet/day              | 10      |
| Redoxon Advanced Immune Support Effervescent Tablets                       | 1 tablet/day              | 10      |
| Redoxon Triple Action Effervescent Tablets                                 | 1 tablet/day              | 10      |
| Seven Seas Jointcare Max   | 1 tablet/day              | 10      |
| Seven Seas Omega-3 Fish Oil plus Cod Liver Oil plus Garlic                 | 1 capsule/day             | 10      |
| Centrum Fruity Chewables   | 2 tablets/day             | 12      |
| Regenovex Actiflex Capsules  | 2 capsules/day            | Unknown |
| Seven Seas Jointcare Active  | 2 tablet/day              | 20      |
| Seven Seas Jointcare Complete  | 2 tablet/day              | 20      |
| Seven Seas Jointcare Supplex   | 2 capsules/day            | 20      |
| Centrum MultiGummies - Adults  | 2 gummies/day             | 20      |
| Centrum MultiGummies - Energy Release                                      | 2 gummies/day             | 20      |
| Centrum MultiGummies Immunity Support                                      | 2 gummies/day             | 20      |
| Vitabiotics Ultra Vitamin D 1000 IU Optimum Level                          | 1 tablet/day              | 25      |
| Vitabiotics Ultra Vitamin D 2000 IU Extra Strength                         | 1 tablet/day              | 50      |
| Vitabiotics Ultra Vitamin D 3000 IU Super strength                         | 1 tablet/day              | 75      |
| Super Strength Vitamin D3 Tablets – 4000 IU                                | 1 tablet/day              | 100     |
| Zahler, Vitamin D3, 50,000 IU, 120 Capsules                                | 1 capsule/week            | 1,250   |
| <b>Supplements aimed at pregnant women</b>                                 |                           |         |
| Sanatogen Pregnancy Mum to Be  | 1 tablet                  | 10      |
| Seven Seas Pregnancy   | 1 tablet/day              | 10      |
| Seven Seas Pregnancy Plus Follow On  | 1 tablet<br>1 capsule day | 10      |
| Vitabiotics Pregnacare Max   | 2 tablets/day             | 10      |
| <b>Supplements aimed at women attempting conception</b>                    |                           |         |

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|  |               |    |
|--|---------------|----|
| Seven Seas Trying for a Baby                     | 1 tablet/day  | 5  |
| Vitabiotics Pregnacare before conception         | 1 tablet/day  | 20 |
| <b>Supplements aimed at breast-feeding women</b> |               |    |
| Vitabiotics Pregnacare breast-feeding            | 2 tablets/day | 10 |
| *Vitamin D <sup>2</sup>                          |               |    |

Table A2: List of fortified foods (Bea that contain vitamin D, taken from supermarket website (Sainsbury's, Tesco, 2020).

| Product Name   | Concentration of Vitamin D (µg/per 100g) | Concentration of vitamin D (µg/kg) |
|--|--|------------------------------------|
| <b>Margarine and fat spreads</b>                     |  |                                    |
| Sainsbury's Olive Spread 500g                        | 5  | 50                                 |
| Sainsbury's Butterlicious Spread 500g                | 5  | 50                                 |
| Sainsbury's Olive Spread 1kg                         | 5  | 50                                 |
| Sainsbury's Olive Lighter Spread 500g                | 5  | 50                                 |
| Bertolli Original Spread 500g                        | 7.5                                      | 75                                 |
| Flora Light Spread 500g                              | 7.5                                      | 75                                 |
| I Can't Believe Its Not Butter! Original Spread 500g | 7.5                                      | 75                                 |
| Stork Original Spread 50                             | 7.5                                      | 75                                 |
| Bertolli Light Spread 500g                           | 7.5                                      | 75                                 |
| Pure Dairy Free Vegan Sunflower Spread 500g          | 7.5                                      | 75                                 |
| Flora Original Spread 500g                           | 7.5                                      | 75                                 |
| I Can't Believe Its Not Butter! Light Spread 500g    | 7.5                                      | 75                                 |
| Bertolli Spread With Butter 400g                     | 7.5                                      | 75                                 |
| I Can't Believe Its Not Butter! Original Spread 1kg  | 7.5                                      | 75                                 |
| Benecol Buttery Spread 500g                          | 7.5                                      | 75                                 |
| Pure Dairy Free Vegan Olive Spread 500g              | 7.5                                      | 75                                 |
| Flora Pro-Activ Olive Spread 500g                    | 7.5                                      | 75                                 |
| Benecol Olive Spread 500g                            | 7.5                                      | 75                                 |
| Sainsbury's Sunflower Spread 500g                    | 7.5                                      | 75                                 |
| Flora Pro-Activ Buttery Spread 250g                  | 7.5                                      | 75                                 |
| <b>Breakfast cereals</b>                             |  |                                    |
| Nestle Multigrain Cheerios Cereal 600g               | 2.5                                      | 25                                 |
| Nestle Honey Cheerios Cereal 565g                    | 2.5                                      | 25                                 |
| Nestle Nesquik Chocolate Cereal 375g                 | 2.5                                      | 25                                 |



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|   |      |      |
|---|------|------|
| Cookie Crisp Chocolatey Chip<br>Cookie Cereal 500g                  | 2.6  | 25   |
| Kellogg's All-Bran Fibre<br>Crunch Berry Burst Cereal<br>390g       | 2.7  | 27   |
| Nestle Curiously Cinnamon<br>Cereal 375g                            | 3.14 | 31.4 |
| Sainsbury's Choco Rice Pops<br>375g                                 | 3.2  | 32   |
| Sainsbury's Balance Flakes<br>Honey & Oats 500g                     | 4.1  | 41   |
| Ready Brek Smooth Porridge<br>Oats Original 450g                    | 4.3  | 43   |
| Weetabix Weetos Chocolatey<br>Cereal 500g                           | 4.3  | 43   |
| Weetabix Crispy Minis Fruit &<br>Nut 600g                           | 4.3  | 43   |
| Weetabix Crunchy Bran Cereal<br>375g                                | 4.3  | 43   |
| Sainsbury's Ready Oats 750g   | 4.3  | 43   |
| Sainsbury's Balance With Red<br>Fruit Cereal 375g                   | 4.8  | 48   |
| Kellogg's Special K Protein<br>Nuts Clusters & Seeds Cereal<br>320g | 4.8  | 48   |
| Kellogg's Coco Pops Rocks<br>Cereal 350g                            | 5    | 50   |
| Sainsbury's Wholegrain<br>Malties Cereal 750g                       | 5    | 50   |
| Sainsbury's Multigrain Hoops<br>Cereal 375g                         | 5    | 50   |
| Sainsbury's Balance Cereal<br>500g                                  | 5    | 50   |
| Sainsbury's High Fibre Bran<br>500g                                 | 5    | 50   |
| Sainsbury's Rice Pops 375g  | 5    | 50   |
| Sainsbury's Choco Hoops<br>Cereal 375g                              | 5    | 50   |
| Sainsbury's Honey Hoops<br>Cereal 375g                              | 5    | 50   |
| Sainsbury's Multigrain Cereal<br>Flakes & Fruit 500g                | 5    | 50   |
| Kellogg's Special K Oats &<br>Honey Cereal 420g                     | 5    | 50   |
| Kellogg's All-Bran Golden<br>Crunch Cereal 390g                     | 5.5  | 55   |
| Kellogg's Fruit n Fibre Cereal<br>700g                              | 6.3  | 63   |
| Kellogg's All-Bran Cereal 750g                                      | 6.3  | 63   |

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|   |      |     |
|---|------|-----|
| Kellogg's Special K Peach & Apricot Cereal 360g       | 7.9  | 79  |
| Kellogg's Special K Red Berries Cereal 500g           | 8    | 80  |
| Kellogg's Corn Flakes Cereal 550g                     | 8.4  | 84  |
| Kellogg's Special K Original Cereal 375g              | 8.4  | 84  |
| Kellogg's Rice Krispies Multigrain Shapes Cereal 350g | 8.4  | 84  |
| Kellogg's Crunchy Nut Cereal 1.1kg                    | 8.4  | 84  |
| Kellogg's Frosties Cereal 500g                        | 8.4  | 84  |
| Kellogg's Bran Flakes Cereal 500g                     | 8.4  | 84  |
| <b>Dried Milk</b>                                     |      |     |
| Tesco Instant Dried Skimmed Milk 340G                 | 0.15 | 1.5 |
| Sainsbury's Skimmed Milk Powder 300g                  | 0.42 | 4.2 |
| Marvel Dried Skimmed Milk 278g                        | 4.6  | 46  |
| <b>Evaporated milk</b>                                |      |     |
| Sainsbury's Evaporated Milk 410g                      | 2.6  | 26  |
| Carnation Topping Evaporated Milk 410g                | 2.9  | 29  |

## Search terms

**“Vitamin D supplementation” AND “pregnancy”**

(01/2015 – 11/2021)

**“Vitamin D supplementation” AND “lactation ”**

(11/2005 – 11/2020)

**“Vitamin D” AND “preconception”**

(11/2005 - 11/2020)

**“Vitamin D” AND “fertility” OR “pregnancy chances”**

(11/2005 – 11/2020)

**“Vitamin D” AND “birth outcomes”**

(12/2000 – 11/2020)

**“Hypervitaminosis” D AND “pregnancy”**

(12/2000 – 11/2020)

**“Hypervitaminosis D” AND “lactation”**

(12/2000 – 11/2020)

**“Hypercalcemia” AND “vitamin D” AND “lactation”**

(12/2005 – 11/2020)

**"Hypercalcemia" AND "vitamin D" AND "pregnancy"**

(12/2005 – 11/2020)

**“Fetal hypercalcemia AND vitamin D”**

(12/2000 – 11/2020)

**“1,25 dihydroxyvitamin D” OR “1,25(OH)2D” AND “pregnancy”**

(12/2000 – 11/2020)

**1,25 dihydroxyvitamin D” OR “1,25(OH)2D” AND “lactation”**

(12/2000 – 11/2020)

**“1,25 dihydroxyvitamin D” OR “1,25(OH)2D” AND “birth outcomes”**

(12/2000 – 11/2020)