



# Report of the Scientific Committee of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) in relation to vitamin D supplementation in the diet of children aged 0 to 3 years

## Section of Food Safety and Nutrition

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## Abstract

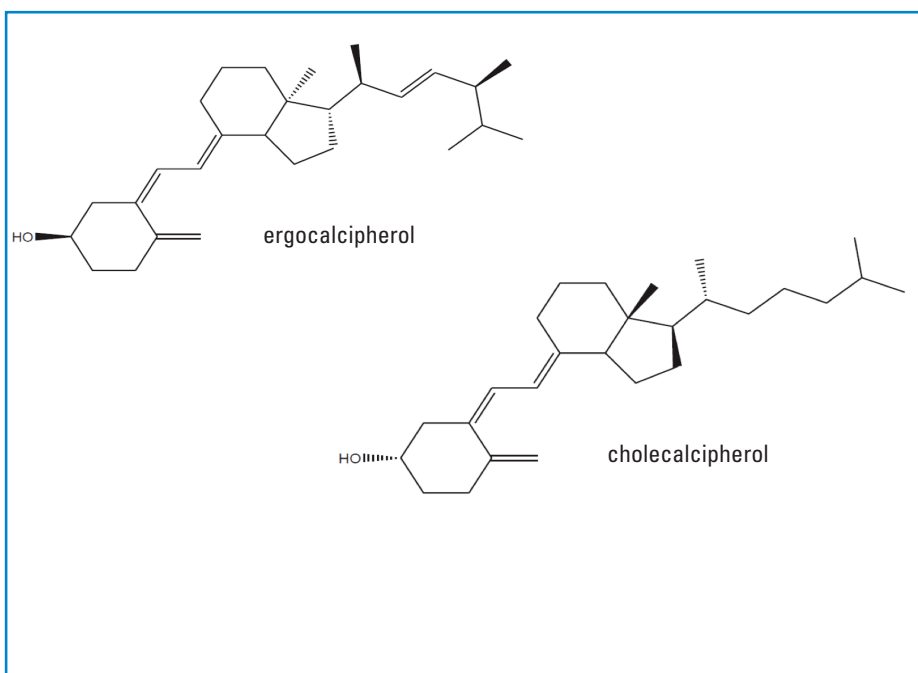
Vitamin D is necessary for both healthy bones and muscles, and for various physiological mechanisms, and a lack of vitamin D is associated with several illnesses. Therefore, a daily intake is recommended to ensure 25-hydroxicholecalciferol serum levels of 20 ng/ml (50 nmol/l). This can be obtained through the diet or be synthesized in the skin, but solar radiation incident vary according to country and region, and the ability to synthesize reduces with age, so diet supplementation with vitamin D could be recommended. Most of the studies on vitamin D intake in European children show that this intake is lower than recommended; the majority of European countries, international organizations and scientific communities therefore recommend supplementing the diet with vitamin D, and have also defined the maximum tolerated levels of this vitamin. They recommend consuming food rich in vitamin D, a reasonable amount of sun exposure and practising physical activities in the open air, so as to obtain 20 mg/ml or 50 nmol/l serum levels of 25(OH)D. If not, a supplement of up to 400 UI/day (10 µg/day) is recommended, under strict medical or paediatric supervision, especially during breastfeeding. The dose can be adjusted to each individual's characteristics, whilst kept below the maximum tolerated level.

## Key words

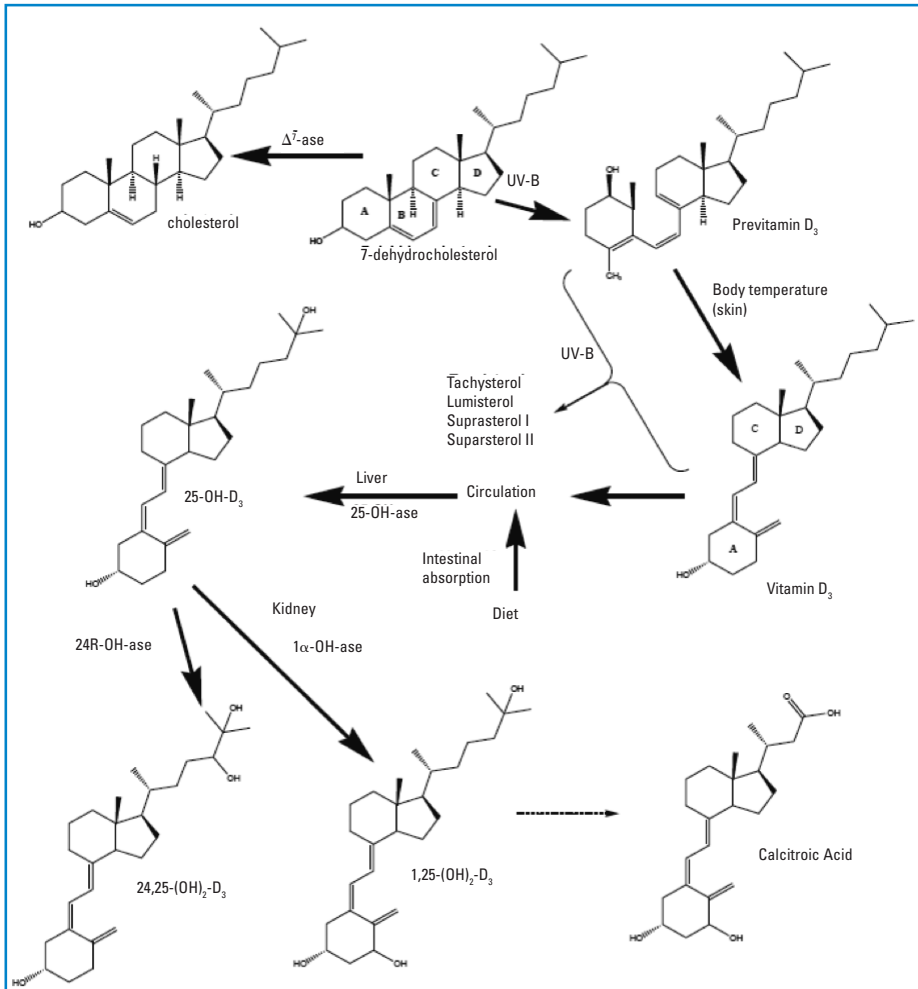
Vitamin D, cholecalciferol, 1,25-dihydroxycholecalciferol, food supplements, children aged 0-3 years.

## 1. Introduction

Vitamin D or calciferol is the name of a group of liposoluble secosterols, whose major forms (Figure 1) are vitamin D<sub>2</sub> or ergocalciferol, produced by UV irradiation of yeast or fungi or found in plants contaminated with the above (Lips, 2006) (Jäpelt and Jakobsen, 2013), and vitamin D<sub>3</sub> or cholecalciferol, which is synthesised in the skin from 7-dehydrocholesterol when it is exposed to UV radiation (Webb, 2006), rapidly forming the previtamin D<sub>3</sub> which, as a result of the action of the skin temperature, produces vitamin D<sub>3</sub>. Irradiation may also lead to the formation of the inactive compounds lumisterol, tachysterol and suprasterol I and II (Bikle, 2011), which will prevent an excess synthesis of vitamin D<sub>3</sub> due to prolonged sun exposure; the previtamin D<sub>3</sub> can revert back to 7-dehydrocholesterol when the levels of the previtamin are reached and the lumisterol can form previtamin D<sub>3</sub> when levels of the latter fall (Figure 2). Vitamin D<sub>3</sub> can also be obtained through diet, mainly from fish, eggs and dairy products, and is absorbed in the small intestine, where it is incorporated into the chylomicrons with other fat molecules, and reaches the blood circulation via the lymphatic system. It is then metabolised in the peripheral tissues that express lipoprotein lipase, particularly adipose tissue and skeletal muscle. It may then act locally or be redistributed in other plasma carriers such as the vitamin D-binding protein (DBP), albumin and lipoproteins, to reach the liver where the metabolism starts (Haddad et al., 1993).



**Figure 1.** Chemical structure of the major forms of vitamin D. **Adapted from:** (UK-COT, 2015).



**Figure 2.** Route followed by vitamin D from its synthesis or intake until its metabolic transformation. **Adapted from:** (UK-COT, 2015).

In the absence of dietary supplements, the majority of the circulating vitamin D<sub>3</sub> is synthesised in the skin. Solar exposure sufficient to cause a minimum reddening of the skin (or minimal erythema dose) can generate 250-500 µg of circulating vitamin D<sub>3</sub> within 24 hours. The duration of exposure that is needed to produce vitamin D will depend on the skin pigmentation of each human race; in this way, the greater the pigmentation, the lower the level of vitamin D formation per exposure time, and the longer the time required to synthesise the same quantity of vitamin (Hollis, 2005). The synthesis of vitamin D in the skin can be conditioned by the geographical latitude, the season, the use of sunscreen and the clothing, as they modify the intensity of solar exposure. Unlike in Spain, some countries have very low levels of sunlight for long periods of the year, and even in Spain the hours of sunshine vary with the region. Furthermore, the capacity of the skin to synthesise vitamin D decreases with age (MacLaughlin and Holick, 1985). A high prevalence of vitamin D

deficit has also been observed among the obese child population with a multifactor aetiology. In this population, deficient levels of vitamin D may affect the development of insulin-resistance and type 2 diabetes mellitus (Gutiérrez-Medina et al., 2014). Therefore, in these cases, dietary supplements of vitamin D may be recommended.

Regardless of its origin, vitamin D requires metabolic transformation to become active, converting in the liver to 25-hydroxyvitamin D and in the kidney the active metabolite 1,25-dihydroxyvitamin D or calcitriol through the action of the parathyroid hormone (PTH) stimulated by low levels of calcium (Bendik et al., 2014). Both forms of vitamin D may vary only because their molecule contains different aliphatic chains, but this does not imply substantial differences in terms of their physiological effects. When there is enough 1,25-dihydroxyvitamin D, calcium levels are high or there is a reduction in the levels of PTH. In the kidney, the metabolite 1,25-dihydroxyvitamin D metabolises to 1,24,25-trihydroxyvitamin D and calcitric acid and the 25-hydroxyvitamin D metabolises to 24,25-dihydroxyvitamin D (IOM, 2011). Vitamin D metabolites are excreted through the bile and faeces and, to a lesser extent, through the urine (Jones, 2008).

Vitamin D is involved in calcium and phosphate metabolism, it is essential for good bone and muscle health, together with other physiological mechanisms, such as the cell differentiation of numerous organs. Vitamin D deficiency has been associated with rickets in children and osteomalacia in adults, a higher risk of infection, autoimmune diseases, insulin resistance, diabetes, metabolic syndrome, cardiovascular and neoplastic diseases, obesity, asthma and certain neurological diseases (Hypponen et al., 2001) (Holick, 2004) (Bouillon et al., 2006) (Lappe et al., 2007) (Thorne and Campbell, 2008) (Blanco et al., 2009) (Sharief et al., 2011) (Maalmi et al., 2012) (Masvidal Aliberch et al., 2012) (Morales et al., 2012) (Xiao-Mei et al., 2012) (Brouwer-Brolsma et al., 2013) (Autier et al., 2014) (Shanmugalingam et al., 2014). Moreover, vitamin D is much more than just a vitamin, as it contributes to the modulation of the immune system (Jones et al., 2012) (Muehleisen and Gallo, 2013); it forms part of a hormone-activated system via specific receptors existing in different cells of the body involving certain genes in their expression (Bosse et al., 2009). In light of the above, a daily intake of 400 IU/day (10 µg/day) is recommended to provide serum levels of 25-hydroxycholecalciferol of 20 ng/ml (50 nmol/l). This intake may be increased according to the age or functional status and/or pathology of the person.

In the first years of life, an adequate nutritional input is particularly essential to cover the physiological needs of this stage given that development is very fast.

Both breastfeeding and artificial feeding of the infant in the first years of life, followed by a varied and balanced diet, may not be sufficient to meet the vitamin requirements, essential for the correct working of the body. In fact, breast milk only provides 10-80 IU/day or 0.25-2 µg/day of vitamin D and there may be significant variations, depending on the maternal deposits during pregnancy, the lactating women's diet and her exposure to sunlight (EFSA, 2014). Vitamin D deposits in premature babies are lower than in those born at full-term, not only due to the lower gestational age, but also to the reduced quantity of fat and muscle, the main areas where vitamin D is stored (AECOSAN, 2005) (Agostoni et al., 2010). Children of strict vegetarian mothers who are being breastfed will display a vitamin D deficit due to a maternal diet deficient in food of animal

origin, the main supplier of this vitamin, especially if the mother is not exposed to sunlight, as the fear of neoplastic skin disorders has reduced levels of exposure to sunlight, even in countries where this would permit the vitamin to be easily synthesised (Munns et al., 2006) (Pallàs Alonso, R. and Grupo PrevInfad/PAPPS, 2006) (Craig, 2009) (Baig et al., 2013).

If, after assessing the usual daily intake in infants aged between 0 and 3 years (breast milk, infant formula, cereals or baby food...), and the circulating levels of 25-hydroxy-vitamin D and comparing these with current recommendations, it is deduced that the intake of vitamin D in the infant or preschool child is inadequate, the use of fortified food or food supplements may be considered in order to prevent nutritional deficiencies and their subsequent consequences.

Nevertheless, the extrapolation of the results based on studies on adults to infants and children requires careful consideration, especially in terms of guaranteeing an adequate nutritional intake of vitamin D, which should be adequately far from the tolerable upper intake level (TUL) (FSA, 2003).

Consequently, the Management Board of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) has asked the Section of Food Safety and Nutrition of the Scientific Committee to conduct a review and analysis of dietary supplementation with vitamin D for infants aged between 0 and 3 years.

## 2. Recommendations for supplementing diet with vitamin D in other countries

Overall, most of the studies on the intake of vitamin D in European children show that this intake is lower than 10 µg/day and is reduced during the second year of life to values of around 5 µg/day (range 4.5-10.4 µg/day). In older age groups, it is around 2 µg/day (EFSA, 2013) (Dalmau et al., 2014). The ENALIA study (National Dietary Survey on the Child and Adolescent Population) suggests that the usual intake of vitamin D in the Spanish child population is 3.3 µg/day in males and 3.0 µg/day in females aged from 6 to 12 months and 2.6 µg/day in males and 2.3 µg/day in females aged between 1 and 3 years (AECOSAN, 2015). These intakes are insufficient to meet the requirements in almost all the population. Up to the age of 3, the main source of vitamin D is infant formula.

In Finland, 47-86 % of the children aged between 1 and 3 years use vitamin D supplements, with a contribution of 6-7 µg/day to the daily intake of vitamin D. In Germany, supplements represent almost half of the daily intake of the children with a similar age. Furthermore, 97 % of Danish children supplement their diet with 10 µg/day; 88 % of Polish children aged 6 months and 70 % of those aged 12 months receive more than 10 µg/day and British children aged between 1.5 and 4.5 years take 1.2 µg/day (including supplements). Greek children, on the other hand, do not supplement their diet with vitamin D and show serum levels of 25(OH)D lower than 50 nmol/l in the first 6 months of life (48±7 nmol/l in summer and 33±4 nmol/l in winter). Therefore, 10-30 % of European children reveal, on balance, clear vitamin D deficiencies (EFSA, 2013). This indicates that the daily intake of vitamin D in children, whether in the diet or as a result of skin synthesis, is clearly inadequate.

The recommendations for supplementing diet with vitamin D in the countries with a social, economical and geographical environment close to Spain, by age and the requirements of the subjects, are shown in Table 1.

<b>Table 1.</b> Recommendations for supplementing diet with vitamin D in different countries		
<b>Country</b>	<b>Age</b>	<b>Recommended supplementation</b>
Germany	2nd week-2nd summer	400-500 IU/day (10-12.5 µg/day)
	0-12 months	400 IU/day (10 µg/day)
	1-15 years	200 IU/day (5 µg/day)
Austria <sup>2</sup>	0-3 years (1st year and 2nd winter)	400-800 IU/day (10-20 µg/day)
Belgium <sup>2</sup>	Infants	400 IU/day (10 µg/day) only children fed with breast milk. Infant formulae already contain an obligatory supplement of vitamin D
Bulgaria <sup>2</sup>	0-3 years	800 IU/day (20 µg/day)
Cyprus <sup>2</sup>	-	No recommendations made
Croatia <sup>2</sup>	-	No recommendations made
Denmark <sup>3</sup>	Full-term infants (37 weeks): 2 weeks-2 years Premature children: from discharge to 2 years	400 IU/day (10 µg/day) Children with dark skin and/or whose body is fully clothed in the summer continue with 400 IU/day (10 µg/day) throughout infancy and probably for their whole life, depending on the level of exposure to sunlight There is no reason to select a product with a higher quantity of vitamins and minerals The intake of vitamin D must be controlled throughout the school years and forms part of the children health reports
Slovakia <sup>4</sup>	0-12 months	400 IU/day (10 µg/day)
	1-6 years	480 IU/day (12 µg/day)
Slovenia <sup>2</sup>	1 week-18 years	400 IU/day (10 µg/day)
Estonia <sup>2</sup>	0-2 years	400 IU/day (10 µg/day)
Finland <sup>5</sup>	2 weeks-2 years	400 IU/day (10 µg/day)
	2-17 years	300 IU/day (7.5 µg/day)

**Table 1.** Recommendations for supplementing diet with vitamin D in different countries

France <sup>6</sup>	Infants	1 000-1 200 IU/day (25-30 µg/day)
	Children <18 months	600-800 IU/day (15-20 µg/day) if they drink milk fortified with vitamin D
	Children <18 months	1 000-1 200 IU/day (25-30 µg/day) if they do not drink milk fortified with vitamin D
	Children 18 months-5 years	2 quarterly doses of 80 000-100 000 IU/day (2 000-2 500 µg/day) every winter (November-February)
Greece <sup>2</sup>	-	No recommendations made
Holland <sup>2,7</sup>	2-24 weeks	400-600 IU/day (10-15 µg/day) with exclusive breastfeeding
	6 months-4 years	400-600 IU/day (10-15 µg/day)
Hungary <sup>8</sup>	2 weeks-1 year	400 IU/day (10 µg/day)
	1-1.5 years	400 IU/day (10 µg/day) in Autumn
Ireland <sup>2,9</sup>	0-12 months	200 IU/day (5 µg/day)
Iceland <sup>2</sup>	1-36 months	400 IU/day (10 µg/day) via vitamin A+D product
Italy <sup>2</sup>	-	No recommendations made
Luxembourg <sup>2</sup>	-	No recommendations made
Norway <sup>2</sup>	<6 months	200-400 IU/day (5-10 µg/day) per supplement or cod liver oil
Poland <sup>10</sup>	0-6 months	400 IU/day (10 µg/day)
	6-12 months	400-600 IU/day (10-15 µg/day) according to diet
	12-36 months	From September to April: 600-1 000 IU/day (15-25 µg/day) according to body weight
	12-36 months	All year or if skin synthesis has not been achieved during the summer: 600-1 000 IU/day (15-25 µg/day) according to body weight
	Risk groups:	
	Premature children (≤40 weeks)	400-800 IU/day (10-20 µg/day)
	Obese children	From September to April: 1 200-2 000 IU/day (30-50 µg/day) according to obesity severity
	Obese children	All year or if skin synthesis has not been achieved during the summer: 1 200-2 000 IU/day (30-50 µg/day) according to obesity severity
	Therapeutic doses (1-3 months): Deficit of 25(OH)D <20 ng/ml (<50 nmol/l)	
	Neonates	100 IU/day (2.5 µg/day)
1-12 months	1 000-3 000 IU/day (25-75 µg/day)	
>12 months	3 000-5 000 IU/day (75-125 µg/day)	
United Kingdom <sup>2</sup>	6 months-4 years	300 IU/day (7.5 µg/day)

Czech Republic <sup>11</sup>	15 days-1 year+winter 2nd year	500 IU/day (12.5 µg/day)
Romania <sup>2</sup>	0-3 years	400 IU/day (10 µg/day)
Sweden <sup>12</sup>	1 week-<2 years	400 IU/day (10 µg/day)
	>2 years	400 IU/day (10 µg/day) if they have dark skin, do not go outside or go outside with the body covered, do not eat vitamin D enriched food, do not eat fish
Switzerland <sup>13</sup>	1st year	400 IU/day (10 µg/day)
	2nd-3rd years	600 IU/day (15 µg/day)
Canada <sup>14</sup>	All year	In children over the age of 1 year or when vitamin D is received from another source (equivalent to 400 IU/day, 10 µg/days) supplementation will be stopped
	Winter (in infants and children at risk)	800 IU/day (20 µg/day)
United States <sup>15</sup>	0-2 months	200 IU/day (5 µg/day)
	>2 months	400 IU/day (10 µg/day)

**Source:** <sup>1</sup>(OGKJ, 2008) (Wabitsch et al., 2011). <sup>2</sup>Response from EFSA focal points in Austria, Belgium, Bulgaria, Cyprus, Croatia, Slovenia, Estonia, Greece, Holland, Ireland, Iceland, Italy, Luxembourg, Norway, the United Kingdom and Romania. <sup>3</sup>(DHMA, 2012) (Nordisk Ministerråd, 2014). <sup>4</sup>(Batelino, 2010) (UVZRS, 2010). <sup>5</sup>(VRN, 2014a,b). <sup>6</sup>(SFP, 2012). <sup>7</sup>(Gezondheidsraad, 2008). <sup>8</sup>(SKP, 2010). <sup>9</sup>(FSAI, 2007, 2011). <sup>10</sup>(Pludowski et al., 2013) (Lifschitz, 2014) (Weker and Baranska, 2014). <sup>11</sup>(Bêlohlávková et al., 2014). <sup>12</sup>(NFAS, 2011). <sup>13</sup>(FCN, 2012) (OFSP, 2012). <sup>14</sup>(CPSI/IHC, 2002) (Ward, 2005) (Health Canada, 2012). <sup>15</sup>(Gartner and Greer, 2003) (Wagner and Creer, 2008) (IOM, 2011).

### 3. Recommendations for supplementing the diet with vitamin D from international organisations and scientific societies

Table 2 describes the recommendations for supplementing the diet with vitamin D made by different international organisations and scientific societies, by age and the requirements of the subjects.



**Table 2.** Recommendations for supplementing the diet with vitamin D from international organisations and scientific societies

Organisation/Association	Age	Recommended supplementation
European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) <sup>1</sup>	0-12 months	400 IU/day (10 µg/day) under strict control of doctor or paediatrician
FAO/WHO <sup>2</sup>	0-18 years	200 IU/day (5 µg/day)
Prevention during infancy and adolescence of the Spanish Association of Primary Paediatric Health Care (Previnfad, AEPap) <sup>3</sup>	In children at risk (premature, with dark skin, inadequate exposure to sunlight due to cultural habits or due to use of sunscreen on all infant walks outside, breastfeeding infants with strict vegetarian mothers)	200-400 IU/day (5-10 µg/day)
Breastfeeding Commission and Nutrition Commission of AEPap <sup>4</sup>	0-12 months	400 IU/day (10 µg/day) total recommended intake
	1-3 years	600 IU/day (15 µg/day) total recommended intake
	4-8 years	600 IU/day (15 µg/day) total recommended intake
	9-18 years	600 IU/day (15 µg/day) total recommended intake
American Academy of Paediatrics (AAP) <sup>5</sup>	<1 year	400 IU/day (10 µg/day) except if they drink milk fortified with vitamin D
	>1 year	400 IU/day (10 µg/day)
EFSA <sup>6</sup>	0-6 months (with exclusive breastfeeding)	400 IU/day (10 µg/day)
	6-12 months (with minimum exposure to sunlight)	400 IU/day (10 µg/day)
	12-<36 months (with minimum exposure to sunlight)	400 IU/day (10 µg/day)

**Source:** <sup>1</sup>(Braegger et al., 2013). <sup>2</sup>(FAO/WHO, 2012). <sup>3</sup>(Pallás Alonso, R. and Grupo Previnfad/PAPPS, 2006). <sup>4</sup>(AEP, 2004) (Martínez Suárez et al., 2012). <sup>5</sup>(Wagner and Creer, 2008). <sup>6</sup>(EFSA, 2013).

#### 4. Tolerated upper intake levels for vitamin D

The Tolerated Upper Intake Levels or TUL defined by the European Food Safety Authority (EFSA, 2012) for vitamin D by age are given in Table 3.

The TUL for vitamin D in adults was calculated from the NOAEL (Non Observable Adverse Effect Level) for the same, considered to be of 275 µg/day (range 234-275 µg/day), the amount that does not lead to hypercalcaemia or hypercalciuria in adults. This value is based in two short-term studies (up to 5 months) on cohorts of young healthy males with a minimum exposure to sunlight (Barger-Lux et al., 1998) (Heaney et al., 2003). To consider the uncertainties associated with this value, an uncertainty factor of 2.5 was selected and the UL was established at 100 µg/day. This TUL was considered applicable to pregnant and lactating women from the data obtained in two studies conducted on pregnant and lactating women, using doses of up to 100 µg/day of vitamin D<sub>2</sub> or D<sub>3</sub> for weeks or months that did not result in any adverse effects for either the mothers or the offsprings (Hollis and Wagner, 2004) (Hollis et al., 2011).

For children and adolescents aged between 10 and 17 years old, the EFSA Panel on the TUL of vitamin D analysed two studies that showed that the intake of vitamin D in doses of up to 50 µg/day does not cause hypercalcaemia (El-Hajj Fuleihan et al., 2006) (Maalouf et al., 2008). Although there are no studies on a higher intake, it has been considered that there is no reason to believe that adolescents at the bone-formation and growth phase have a lower tolerance of vitamin D than adults. Therefore, the same TUL is recommended for adolescents and for adults.

For children between 1 and 10 years of age, there has been no new data since the drafting of the report of the Scientific Committee on Food (SCF, 2003). As a consequence, it was considered that there was no reason to believe that children aged 1-10 years at the bone formation and growth phase had a lower level of tolerance for vitamin D than adults. Therefore, considering their smaller body size, a TUL of 50 µg/day was recommended.

For children under the age of 1 year, there is little data on which a NOAEL or a LOAEL (Lowest Observed Adverse Effect Level) might be based that can be added to the information already provided in the SCF (2003) report and its relation with the appearance of hypercalcaemia in healthy children. Given this limited evidence, the EFSA considered that the TUL of 25 µg/day defined previously should be maintained.

<b>Table 3. Tolerated upper intake levels for vitamin D</b>	
<b>Age (years)</b>	<b>Tolerated Upper Intake Levels (TUL) of vitamin D (µg/day)</b>
0-1	25 (1 000 IU/day)
1-10	50 (2 000 IU/day)
11-17	100 (4 000 IU/day)
≥18 (includes pregnant and lactating women)	100 (4 000 IU/day)

**Source:** (EFSA, 2012).

Different countries and scientific societies have established a TUL for their populations, as shown in Table 4.

**Table 4.** Tolerated upper intake levels for vitamin D described by different countries and scientific societies

Country/Organisation	Age (years)	Tolerated upper intake levels (UL) of vitamin D ( $\mu\text{g/day}$ )
Germany <sup>1</sup>	2-10 years	25 (1 000 IU/day)
Belgium <sup>2</sup>	1-10 years	25 (1 000 IU/day)
Finland <sup>3</sup>	0-5 years	50 (2 000 IU/day)
Scandinavia <sup>4</sup>	0-1 years	25 (1 000 IU/day)
	1-10 years	50 (2 000 IU/day)
Poland <sup>5</sup>	0-1 years	25 (1 000 IU/day)
	1-10 years	50 2 000 IU/day)
	11-18 years	100 (4 000 IU/day)
United Kingdom <sup>6</sup>	<1 year	25 (1 000 IU/day)
	1-10 years	50 (2 000 IU/day)
	>10 years	100 (4 000 IU/day)
Institute of Medicine (IOM, United States) <sup>7</sup>	0-6 months	25 (1 000 IU/day)
	6-12 months	38 (1 520 IU/day)
	1-3 years	63 (2 520 IU/day)
	4-9 years	75 (3 000 IU/day)
	9-8 years	100 (4 000 IU/day)
Breastfeeding Commission and Nutrition Commission of AEPap (Spain) <sup>8</sup>	0-6 months	25 (1 000 IU/day)
	6-12 months	37.5 (1 500 IU/day)
	1-3 years	62.5 (2 500 IU/day)
	4-8 years	75 (3 000 IU/day)
	9-18 years	100 (4 000 IU/day)

**Source:** <sup>1</sup>(Domke et al., 2005) (German Nutrition Society, 2012). <sup>2</sup>(CSS, 2015). <sup>3</sup>(VRN, 2014a,b). <sup>4</sup>(Nordisk Ministerråd, 2014). <sup>5</sup>(Pludowski et al., 2013) (Lifschitz, 2014) (Weker and Baranska, 2014). <sup>6</sup>(UK-COT, 2015). <sup>7</sup>(IOM, 2011). <sup>8</sup>(Martínez Suárez et al., 2012).

These TUL are based on the fact that an excess of vitamin D may cause hypercalcaemia due to the increase in the intestinal absorption and bone resorption of calcium, which may imply a deposit of calcium on soft tissue, bone demineralisation and irreversible renal and cardiovascular toxicity. Clinical signs and symptoms may include anorexia, nausea, vomiting, weakness, lethargy, constipation, unspecified pain and other manifestations including thirst, polyuria, weight loss and arrhythmias. In addition, due to the lipophylia of vitamin D and its retention on the adipose tissue, the effects of vitamin D toxicity may last up to 2 months after exposure to high levels of the

same has stopped. These effects are due, mainly, to repeated administration, as isolated doses, even when high, do not appear to show signs of toxic effects, except when the dose in children reaches 15 000 µg (UK-COT, 2015).

### Conclusions of the Scientific Committee

The Scientific Committee of the AECOSAN, in the light of the scientific information available, concludes that it is necessary to guarantee that the serum levels of 25-hydroxycholecalciferol in children aged 0-3 years old are maintained at 20 ng/ml or 50 nmol/l. This must be obtained from diet, exposure to sunlight and, if necessary, from dietary supplements so that they receive, in total, 400 IU/day (10 µg/day) of vitamin D during the first year of life or 600 IU/day (15 µg/day) between 1 and 3 years of age.

Therefore, it is considered that priority should be given to encouraging the consumption of food rich in vitamin D, including fish, eggs, dairy products or appropriate infant formulae, each one introduced in the dietary pattern of the child in accordance with age.

The performance of physical activity in the open air must also be encouraged, especially among children after the age of 18 months, as under this age, the activity would be walks outside with the mother/father/carer. This serves to ensure optimum solar exposure, using adequate sunscreens that permit the reception of the sunlight while also protecting against its harmful effects, especially in regions and at times of maximum amount of sunshine, although in Spain, except in winter, an exposure of 20 % of the body without any protection between 10 and 15 hours provides the maximum benefits in vitamin D with the lowest risk of skin erythema.

In the event of an inadequate input of vitamin D in the diet or in certain risk groups (premature children, dark skins, obesity, breastfeeding infants with strict vegetarian mothers especially with low levels of exposure to sunlight, children with an inadequate sunlight exposure due to cultural habits or the use of a sunscreen on all of the child's walks) the diet should be supplemented with up to 400 IU/day (10 µg/day) of vitamin D in children aged 0-3 years, either in the form of medicines, supplements or food enriched with this vitamin. This supplement will be especially advisable during breastfeeding, due to the low vitamin D content of breast milk. There is no need to supplement the diet of infants fed with infant formulae, as its composition already meets all the vitamin D requirements.

In any case, this supplementation must be taken under the strict control of the doctor or paediatrician, performing regular tests to ensure that the above-mentioned serum levels are maintained and adapting the supplement to these levels, remaining suitably far from the tolerated upper intake levels.

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