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**Update to 2007 Scientific Committee Report:  
Recommendations for a National Policy on Vitamin D  
Supplementation for Infants in Ireland**



# Update to 2007 Scientific Committee Report: Recommendations for a National Policy on Vitamin D Supplementation for Infants in Ireland

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## Abbreviations

|             |                                |
|-------------|--------------------------------|
| <b>EU</b>   | European Union                 |
| <b>EFSA</b> | European Food Safety Authority |
| <b>HSE</b>  | Health Service Executive       |
| <b>Kg</b>   | Kilogram                       |
| <b>µg</b>   | Microgram                      |
| <b>UL</b>   | Tolerable upper intake level   |
| <b>WHO</b>  | World Health Organization      |

## Background

Breastfeeding represents optimal infant feeding practice (WHO 2003). Despite the many health benefits to infants and mothers, breastfeeding rates are low in Ireland. While infant formula is formulated to be as close as possible to breast milk, it remains substantially inferior. One of the only advantages of infant formula is that it is fortified to provide a minimum amount of vitamin D per 100 kcal, which compares favourably with the negligible amounts of vitamin D provided in breast milk.

In response to the emergence of nutritional rickets among high-risk children in Ireland at the start of this millennium, the Scientific Committee of the FSAI recommended that all infants, (0 to 12 months of age), regardless of how they are fed, should receive a supplement providing 5 µg of vitamin D only (FSAI 2007). Modelling vitamin D intakes from infant formula in addition to the 5µg supplement undertaken in FSAI confirmed that this supplemental level did not result in any infant (birth to 12 months - including those with high intakes of infant formula due to growth along high percentiles) exceeding the Tolerable Upper Intake Level (UL) for vitamin D.

There were many advantages of supplementing all infants (0 to 12 months), both breastfed and formula-fed with a 5µg vitamin D only supplement - including the dissemination of a simple recommendation for all health professionals, but the main advantage was that this approach did not undermine breast feeding. This FSAI recommendation was drafted into health policy by Mary Harney, Minister for Health in 2007. The HSE implemented this national vitamin D supplementation policy for infants aged 0 to 12 months of age in 2010. A recent study, which is the first to conduct a comprehensive evaluation of the policy, indicates that adherence with the infant vitamin D policy in Ireland is high (Hemmingway et al 2019). Research undertaken in Ireland confirmed that the 5 µg vitamin D supplemental level is adequate for healthy term infants who are breastfed - including those with low vitamin D status at birth (Owuneme et al 2012 and 2015)

## Vitamin D levels in Infant Formula set to increase substantially due to new EU legislation

Recently, following advice from EFSA (2014) there has been a change in EU legislation governing the composition of infant formula and this has resulted in a doubling of the minimum amount of vitamin D provided per 100 kcal. It is notable that this EFSA Scientific Opinion did not consider any intake of vitamin D through supplementation (EFSA 2014). Commission Delegated Regulation (EU) 2016/127 comes into force from 22<sup>nd</sup> February 2020 and these legislative changes will result in a significant increase in the vitamin D content of infant formula.

## Continuing to supplement formula-fed infants with 5 µg vitamin D after the legislation changes come into force will result in some infants exceeding the UL for vitamin D

Up to now infant formula is manufactured to provide vitamin D at a level between the minimum (1µg/100kcal) and maximum levels (2.5µg/100kcal) set out in Annex 1 of Commission Directive 2006/141/EC, which sets out the essential composition of infant formula in the final product ready for consumption. This sets a minimum level of 1µg for vitamin D and provides for levels to be added up to a maximum of 2.5µg/100kcal (infant milk products currently on the Irish market<sup>1</sup> contain varying amounts of vitamin D ranging from 1.4µg – 1.9µg/100kcal).

The new legislation, Commission Delegated Regulation (EU) 2016/127, will result in the reformulation of all infant formula products currently on the Irish market to reach a higher minimum vitamin D level of 2µg/100kcal. This will lead to an increase in the amount of vitamin D infants will receive from infant formula.

In response to concerns from Member States, including Ireland, the EU Commission requested further advice from EFSA regarding formula-fed infants, supplements and UL for vitamin D. In this second EFSA Opinion (EFSA 2018) it was noted that the proposed increase also to the **maximum vitamin D** composition may result in some infants with high intakes of formula (i.e. those larger infants at 4 months of age) exceeding the UL for vitamin D (see EFSA Opinion 2018 Table 9 page 59). This resulted in a slight reduction in the maximum level of vitamin D permitted (reduced back to 2.5µg/100kcal) and the minimum level remained at 2µg/100kcal.

Thus as companies begin to reformulate products in line with Commission Delegated Regulation (EU) 2016/127, infant formula will provide significantly more vitamin D per 100 kcal than before. This has implications for the policy in Ireland which recommends all infants (including formula-fed infants) receive a daily 5µg vitamin D supplement. This policy needs to be reviewed

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<sup>1</sup> 2019. Brand names have been removed from this public document.

## Recommendations

### Vitamin D\* supplementation

#### Option 1.

- A daily 5µg vitamin D-only supplement should be given to all healthy term breast-fed infants from birth to 12 months
- A daily 5µg vitamin D-only supplement should be given to healthy term breast-fed infants (0-12 months) **who consume no more than 300ml of formula<sup>2</sup>/day** (i.e. infants who are fed a combination of breast milk and formula)
- Formula<sup>2</sup>-fed infants should not receive a daily vitamin D supplement or any supplement containing vitamin D, as there are adequate amounts of vitamin D added to formula.

#### **Rationale for choosing 300 ml as the amount of infant formula as a cut off**

Using the legislative tolerances:

- Minimum vitamin D content of infant formula = 2 µg vitamin D/100 kcal  
2 µg vitamin D/100 kcal is equivalent to 1.33 µg/100 ml  
376 ml Infant formula will provide 5 µg vitamin D
- Maximum vitamin D content of infant formula = 2.5 µg vitamin D/100 kcal  
2.5 µg vitamin D/100kcal is equivalent to 1.66 µg/100 ml  
301 ml Infant formula will provide 5 µg vitamin D

**Therefore, a range of 301 to 376 ml of infant formula provides 5 µg vitamin D and 300 ml will protect infants (receiving formula containing the maximum permitted amount of vitamin D) from overexposure to vitamin D**

Note:

Maximum vitamin D content of follow-on formula is 3 µg vitamin D/100 kcal  
3 µg vitamin D/100 kcal is equivalent to 1.99 µg/100 ml  
251 ml follow-on formula will provide 5 µg vitamin D

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\* The form of vitamin D supplement that is preferable is vitamin D3. However, for those who wish to avoid foods of animal origin vitamin D2 is also suitable.

<sup>2</sup> Infant Formula and Follow-on Formula

## Option 2.

Only breast-fed infants should be given a daily 5µg vitamin D\* supplement. Formula<sup>2</sup>-fed infants should not be given any supplement containing vitamin D.

- A daily 5µg vitamin D-only supplement should be given to all healthy term breast-fed infants from birth to 12 months
- Exclusively bottle-fed infants should not be given any supplement containing vitamin D (i.e. a vitamin D only supplement or a multi-vitamin containing vitamin D)

### Rationale for Option 2

There is no need to recommend a vitamin D supplement be given to infants who are fed a combination of breast milk and infant formula because infant formula is a rich source of vitamin D (providing 1.33 to 1.66 µg vitamin D per 100 ml; 100ml is a very small amount of formula). Partially breast-fed infants receiving a daily 5 µg vitamin D supplement will have stores of vitamin D to cover requirements until they are receiving 300ml of formula per day. Furthermore, EFSA recommends 200ml and 260ml/kg/day as conservative mean and high level infant formula consumption values, respectively, to be used for performing risk assessments for infants below 16 weeks of age (EFSA 2017). Therefore, an infant would be expected to consume 300ml/day within the first few days of life, which would provide 5 µg vitamin D.



For more information, please see the [HSE nutritional information on Vitamin D for babies 0 to 12 months here.](#)

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\* The form of vitamin D supplement that is preferable is vitamin D3. However, for those who wish to avoid foods of animal origin vitamin D2 is also suitable.

<sup>2</sup> Infant Formula and Follow-on Formula



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World Health Organisation (WHO) policy of 'exclusive breastfeeding to 6 months and as the main milk up to age 2+ years (providing half or more of child's nutritional needs from 6-12 months and up to one-third during 2<sup>nd</sup> year of life)' (World Health Organisation, UNICEF (2003). Global Strategy for Infant and Young Child Feeding).

## Members of the Vitamin D Expert Group

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