Draft Guidance Note
Criteria for 5µg Vitamin D Supplements to be Listed as Suitable for Infants

(Supporting national policy on vitamin D supplementation of infants in Ireland)

FSAI, 2017

CONTENTS

1. BACKGROUND

All food supplements marketed in Ireland must comply with:

1. all relevant EU legislation*
2. national legislation on food supplements (S.I. 506 of 2007 and S.I. 355 of 2010)

This Guidance Note lays out the criteria for a voluntary process covering vitamin D supplements for infants which food businesses may avail of after placing their product on the Irish market. This voluntary process consists of additional criteria for vitamin D supplement products that are suitable for providing infants with 5µg vitamin D in accordance with national policy. Food supplement products that meet all the criteria outlined in this Guidance Note, in addition to all relevant EU and national legislation, will be listed by FSAI as being suitable for infants in line with national policy.

Vitamin D is important for healthy growth and development of infants. Most countries have a vitamin D supplementation policy in place to ensure infants get enough vitamin D. In Ireland, the national supplementation policy recommends that all infants living in Ireland, regardless of whether breast fed or formula fed, are given a vitamin D only supplement providing 5µg vitamin D (and no other nutrients)[(1)]. While with this approach, breastfed babies do not get as much vitamin D as those who are formula fed, under this policy, they are provided with sufficient vitamin D, whilst also gaining the unique and unrivalled health advantages associated with breast feeding. More detailed information on vitamin D deficiencies in Ireland and the need for vitamin D supplementation of all infants is outlined in Appendix I (sections I - III).

Providing infants with the correct amount of vitamin D is critical. There are many products for infants on the market in Ireland providing varying amounts of vitamin D per day. However, the national policy in Ireland takes into account the background dietary intakes of vitamin D and recommends a low dose (5µg) vitamin D supplement. There is a concern that infants who are given high dose supplements of vitamin D could be put at risk of excessive vitamin D intakes. Continuous excessive vitamin D intakes results in vitamin D toxicity (hypervitaminosis D) which leads to hypercalcemia (high levels of calcium in the blood). This

* https://www.fsai.ie/legislation.html

can lead to complications, especially involving the kidneys[2]. It is imperative that the correct amount of vitamin D is given to infants in Ireland. This requires the following:

1. Use of a vitamin D only supplement providing 5µg/day
2. The actual amount of vitamin D provided by the supplement deviates very little from 5µg/day
3. The product delivery system provides the correct dose
4. The instructions for administering the dose are clear and understandable

For practicable and safe implementation of the national policy of vitamin D supplementation of all infants a voluntary process is required, whereby, vitamin D supplement products that are most suitable are listed by FSAI to inform health care professionals and parents/caregivers. Clear criteria are required to determine which infant vitamin D supplements on the market in Ireland are suitable to support the national policy on vitamin D supplementation for infants in Ireland. An expert working group, led by the FSAI, developed specification criteria to form the basis for determining which vitamin D supplements are most suitable. These criteria and how the voluntary process will work are described in this technical guidance document in draft form. A public consultation on this draft Guidance Note will be held to seek feedback from food supplement business stakeholders, food law enforcement, health care professionals and the general public. This feedback will be used to finalise the Guidance Note on Criteria for 5µg Vitamin D Supplements to be Listed as Suitable for Infants (supporting national policy on vitamin D supplementation of infants in Ireland).

More detailed information on the need for specific criteria on vitamin D supplements suitable for infants in Ireland can be found in Appendix I (section IV).

2. PURPOSES AND SCOPE

The purposes of this Guidance Note are to provide:

1. The applicant[†] with information on how to apply for product(s) inclusion on the list of food supplements[‡] deemed suitable for providing 5µg vitamin D (only) daily to infants in Ireland in line with the National supplementation policy[(1)].
2. Food business operators who have vitamin D product(s) on the list with details of:
    - On-going monitoring of vitamin D listed products
    - Consequences for listed products that fail to meet the specification criteria
    - Action required when changes are made to a listed product

This list will be posted and managed on the FSAI website.

In order to be included in the voluntary process, the Guidance Note provides details on the specifications for:

- Composition
- Delivery system
- Instructions for use
- On-going monitoring required

This is a voluntary process that the food businesses marketing food supplements in Ireland can avail of. It is not a mandatory requirement. Other food supplements not meeting these criteria can also be placed on the market providing they fully comply with EU and national legislation.

[†] The term 'applicant' refers to the commercial entity applying to have the food supplement product listed as being suitable for infants (supporting the national infant vitamin D policy in Ireland)
[‡] The term 'food supplement' refers to vitamin D only food supplements suitable for infants

3. SPECIFICATION CRITERIA

To be considered for inclusion on the list, the product must already be on the market and must meet all the criteria outlined in this chapter.

A. THE APPLICATION PROCESS

I. The applicant must provide the FSAI[§] with product data on:

a) quality control batch analysis to ensure the tolerance range (outlined in section B) is met

b) a summary of batch analysis which includes a description of the batches (lot no., manufacturing date, batch size, pack type/size, best before date, recommended daily dose, amount of vitamin D provided in recommended daily dose, vitamin D assay and Certification of Analysis) (see Appendix II for Batch Analysis Monitoring Form)

Note: This form should be submitted at initial application and when making subsequent applications i.e. if changes have been made to a product.

II. Applications can be submitted throughout the year; however applicants need to be aware that samples of the products will only be tested in February, June and October. Therefore, applications should be made by 31st January, 31st May or 30th September so that they can be sampled in the one of these three time points. This will enable FSAI to complete an assessment of the application within 4 months of the time point in which the application was submitted, on the condition that a complete and valid application was provided by the applicant. Product assessments requiring re-analysis (see section III) may take longer, but less than 6 months.

III. The FSAI, along with the HSE Environmental Health Service (EHS), will arrange for the vitamin D content of random samples of the product to be tested by the HSE Cork Public Analyst's Laboratory (CPAL) at the three time points outlined in section II. Any of these samples found to contain an amount of vitamin D that is

[§] Applications to be sent to: Public Health Nutrition, Food Safety Authority of Ireland, Abbey Court, Lower Abbey Street, Dublin 1, D01 W2H4 or alternatively by email to phn@fsai.ie

not in line with the tolerance range (outlined in section B) will be re-analysed by subcontracting the analysis to an independently accredited laboratory to confirm the results recorded in CPAL.

IV. Following re-analyses, if a product is still found to contain an amount of vitamin D that is outside the tolerance range (outlined in section B), the product will not be added to the list. It is then up to the applicant to determine if this discrepancy relates to the delivery system providing the daily dose, the actual level in the product or a combination of both.

V. The FSAI will send written confirmation to the applicant on the results of the product assessment and whether it will be included on the FSAI list or not.

B. COMPOSITION

I. Form

a) Vitamin D in the product must be delivered in the form of cholecalciferol (D_3)[**].

Note 1: This is the form produced by the skin in humans and is the most potent form of vitamin D.

Note 2: Ergocalciferol (D_2)[††] is also permitted under legislation[‡‡], however in order to meet this specification, cholecalciferol (D_3) is the form required[(3)]. If there is a requirement for vitamin D to be provided by ergocalciferol (D_2), application must be made to FSAI.

b) The product providing vitamin D must be in liquid form.

II. Daily amount (dose) provided

a) The recommended daily amount (dose) of vitamin D provided by the product must be 5µg.

b) The tolerance for vitamin D provided by the product must be no less than 20% below the labelled value and no more than 20% above the labelled value. Therefore, including measurement of uncertainty, the product must provide between ***4 - 6µg*** of vitamin D.

Note: This tight range ensures that all infants are provided with the adequate amount of vitamin D while also safeguarding them from excessive intakes as their normal diet can provide significant amounts of vitamin D.

III. Food additives

The use of additives in food supplements destined for infants are currently not allowed. A list outlining those additives which are permitted is expected within the next year, by June 2018.

Note: This is correct as of June 2017 and will be updated in accordance with EU legislation (relevant legislation can be found at https://www.fsai.ie/legislation/food_legislation/food_additives/introduction.html).

[**] Made in the skin of humans and animals when exposed to sunlight
[††] Made in plants and fungus when exposed to ultra violet light
[‡‡] S.I No. 506 of 2007 European Communities (food supplements) regulations 2007, as amended: https://www.fsai.ie/uploadedFiles/Science_and_Health/European-Communities-Food-Supplements-Regulations-2007.pdf

C. MODE OF DELIVERY AND PRODUCT COMPONENTS

I. The delivery system must be able to accurately deliver the recommended daily amount (dose) of 5µg vitamin D to infants

II. Only one delivery system must be included with the product

III. The labelling must not refer to other or alternative delivery systems

IV. The delivery system must specifically provide 5µg vitamin D. The delivery system should not provide for delivering any other doses for other population sub-groups

V. Suitable delivery systems include a calibrated dropper, pump, a dose-specific syringe, or other effective delivery mechanisms, preferably with the 5µg dose clearly marked

VI. Instructions provided on dosing and using the delivery system must be very clear and easy to follow (see section D)

D. INSTRUCTIONS FOR USE

I. Instructions for use should be in one format only and this should be consistent throughout all the labelling. For example:

   a) *if a dose is described in drops, it should not be described elsewhere in a different measurement unit such as mls*

      Or

   b) *if a dose is described as 0.5 ml, it should not be described as ½ ml elsewhere*

II. Product instructions should exclusively provide for 5µg vitamin D. Instructions for providing any other daily dose must not appear on the product.

III. It is preferable that graphics/pictograms that demonstrate how to accurately deliver the recommended daily amount (dose) of 5µg vitamin D should be included in the labelling.

IV. The instructions for use should be given in plain English that is easy to understand and that meets the National Adult Literacy Agency (NALA) guidelines[§§].

V. The applicant must not use the listing of a product by the FSAI as a promotional tool in commercial communications (whether in the labelling, presentation or advertising) as this would be in breach of health claims regulation and would result in immediate de-listing of the product.

[§§] Available at: https://www.nala.ie/

E. ON-GOING MONITORING OF VITAMIN D LISTED PRODUCTS

I. Monitoring by the food business operators who have vitamin D supplement product(s) listed will ensure:

a) any batches of the listed product(s) are tested to confirm the level of vitamin D falls within the tolerance range (outlined in section B) before being released onto the market.

b) the Batch Analysis Monitoring Form (see Appendix II) is completed for all batches

c) the labelling and marketing of the product(s) are in line with the relevant criteria set out in this document

II. Monitoring by the FSAI and EHS/CPAL will include:

a) Sampling and analysis of random listed vitamin D products as part of on-going official food controls. This laboratory analysis will also ensure listed vitamin D (only) food supplements comply with the labelled value, stated dose and that they fall within the tolerance range as outlined in section B.

4. CONSEQUENCES FOR LISTED PRODUCTS THAT FAIL TO MEET THE SPECIFICATION CRITERIA

I. Products will be immediately removed from the list and the HSE Health and Wellbeing Division (EHS and Health Promotion & Improvement) informed if they do not meet any aspect of the voluntary criteria laid out in this document, in particular if the vitamin D levels provided are found to be outside the stricter tolerance levels outlined in Chapter 3 section B.

II. If the product(s):

a) remain compliant with all food legislation, including the EU tolerance ranges[4], they can remain on the market and no further follow-up action will be taken

or

b) are found to be in breach of any aspect of food legislation, appropriate enforcement action will be taken

III. Products will be immediately removed from the list and the HSE Health and Wellbeing Division (EHS and Health Promotion & Improvement) informed if they fail to comply with any aspect of the relevant EU and national legislation. Products that are in breach of any aspect of food labelling including health claims will be immediately removed from the list and HSE Health and Wellbeing Division (EHS and Health Promotion & Improvement) informed (this applies regardless of the correct amount of vitamin D provided in the product) and appropriate enforcement action will be taken.

Note: *Where a product has been removed from the list, the food business operator will have to re-apply (as outlined in Chapter 3 section A).*

5. ACTION REQUIRED WHEN CHANGES ARE MADE TO A LISTED PRODUCT

I. FSAI must be notified by the food business operator if the labelling, product branding, mode of delivery or formulation of a product already on the list will be subject to change in any way. This will allow for the assessment of the new product when it comes on the market. This will ensure that the old and new products can both be listed to allow for a period of overlap while both products are on the market at the same time.

II. The food business operator must inform the FSAI when the old product is expected to be gone from the market so it can be removed from the list.

III. Products will be removed from the list if the food business operator changes ownership, as approval is only valid for the food business operator making the original application.

IV. It is the duty of the new owner to re-apply to the FSAI (as outlined in Chapter 3 section A) for inclusion of their product on the list.

APPENDIX I – VITAMIN D AND IRELAND

I. Vitamin D deficiency and infants in Ireland

As Ireland is located at latitude 51° to 55° north, very little UVB light reaches the earth's surface resulting in reduced production of vitamin D in the skin, especially during the winter months, i.e. October to March. This fact, in conjunction with low dietary intakes, is compromising the vitamin D status of all groups of the population living in Ireland. As sun exposure is a risk factor for skin cancer, it is not recommended to expose infants to sunlight for the purpose of synthesising vitamin D.

The National Adult and Nutrition Survey[5] was undertaken between 2008-2010 on adults aged 18 years and over in Ireland. As part of this survey, habitual food intake was determined using a four day semi-weighed food record. Participants were asked to record detailed information on the amount and type of all foods, drinks and nutritional supplements consumed over four consecutive days. The survey found that a substantial proportion of adults aged 18-64 years had low vitamin D intakes. Average daily vitamin D intakes of less than 5µg were reported in 72% of men and 78% of women, with over 90% of this age group having daily intakes of less than 10µg. Over half of those aged 65 years and over (59% of men, 58% of women) had mean daily vitamin D intakes of less than 5µg, with 87% of men and 77% of women having daily intakes less than 10 µg. Blood samples were also taken for a proportion of the participants in this study. Cashman and colleagues[6] used this blood data to determine the impact of vitamin D supplement use and season on vitamin D (serum 25(OH)D) concentrations. They found that vitamin D-containing supplement users had significantly higher vitamin D status compared with non-users. However, only 16% of Irish adults (aged 18-64 years) were reported to be consuming vitamin D-containing supplements. It was also found that during winter, the mean serum 25(OH)D concentrations in vitamin D-containing supplement users were similar to the mean concentrations in non-users during summer. This study concluded that vitamin D deficiency (serum 25(OH)D <30nmol/l) occurs in 7% of the population throughout the year while 40% of the population have vitamin D levels considered inadequate for bone health by the Institute of Medicine (serum 25(OH)D <50nmol/l), with the prevalence being much higher in the winter months.

The National Pre-School Nutrition Survey[7] was carried out on children aged 1 to 5 years inclusive and also looked at habitual food intake. This survey determined the proportion of children with vitamin D intakes of less than 5µg and 1µg. Vitamin D intakes were found to be low with 70-84% of 1-5*** year olds having intakes less than 5µg and 17-25% having intakes less than 1µg. This indicates that a significant proportion of children may be at risk of inadequate vitamin D status, particularly during the winter months.

The result of severe and prolonged vitamin D deficiency is rickets, a condition affecting the skeletal system. Rickets impairs the process which leads to mineralisation of the bone and also adversely affects rigidity. Children with rickets may have bowed arms and legs, they may have delayed closure of the fontanels (soft spots) in the skull and the rib-cage may become deformed due to the pulling action of the diaphragm. The age at which rickets is most common is between three and 18 months, and the established risk factors are:

- exclusive breastfeeding without vitamin D supplementation
- low maternal vitamin D status
- low calcium intakes
- living in temperate climates
- dark skin

Rickets was, to a great extent, eradicated in Europe just after the Second World War, although sporadic cases occur from time to time. Alarmingly, there are now documented reports of an increase in the number of rickets cases among children in Ireland. Between the years 2000 to 2005 there were reports of cases of rickets among infants and toddlers attending two paediatric hospitals in Dublin 8[3]. Rickets (due to nutritional inadequacy) represents the extreme end of the spectrum of vitamin D deficiency, indicating a likely higher incidence of undiagnosed vitamin D deficiency in the wider paediatric population in Ireland. This re-emergence of rickets was a contributing factor to the introduction of a National vitamin D supplementation policy in Ireland (section III below).

In 2008, a prospective study investigated the nutritional vitamin D status and the prevalence of suboptimal vitamin D status in a cohort of pregnant Irish women[8]. They found that the mean daily intake of vitamin D among the cohort was 3.6 µg/day with no participants

*** Does not include 5 year olds

achieving the recommended vitamin D intake for Irish pregnant women (10µg/day). When blood levels of serum 25(OH)D were examined collectively over all three trimesters, it was found that 14 - 24% were deficient (<25nmol/L) in vitamin D and 34 - 53% were insufficient (25-50nmol/L). It was also reported that vitamin D status was lowest during the winter period.

Recently, a retrospective audit of clinical vitamin D samples (*n*10,181) obtained over 10 months in 2013 was carried out[(9)]. This study measured serum 25(OH)D concentrations to determine the vitamin D status of the samples. This study found that 24% of samples were at risk of deficiency (<30nmol/L), with 5% being at risk of harm from excessive vitamin D intake levels (>125nmol/L). The remaining 71% fell within the range of adequacy and sufficiency. This study also reported that paediatric sources were among those accounting for the highest prevalence of hypervitaminosis (>125nmol/L) cases.

While it is imperative that deficiency is avoided (especially during times of rapid growth i.e. in infancy and early childhood) it is also vital that excessive intakes are avoided. Special care must be taken for infants especially in how they are fed, whether it is with formula or breastmilk, as the amount of vitamin D varies greatly between the two.

II. Infant feeding practice and implication for vitamin D supplementation

Breast milk is the best source of nutrition for new-born infants. Breast milk contains bioactive substances and is tailor made for infant's needs. Breast milk is unique in that it changes depending on the age of the baby and over the course of the feed. Breast milk is not a natural source of vitamin D (approximately 0.6µg per litre)[(10)]. Infant formula, unlike breast milk has vitamin D added during its manufacture. Infant formula does not provide the same benefits as breast milk as it does not contain the bioactive substances found in breast milk which are protective from disease. This makes recommendations for vitamin D supplementation difficult. Some countries (including Canada) have a policy in place which supplements only breast fed babies as formula fed babies get vitamin D from formula. These countries also tend to have very high breastfeeding rates (~90% in Canada)[(11)]. When breast fed babies are taking a certain amount of formula, supplementation is stopped to prevent babies from getting too much vitamin D. Experience in these countries is that this gives very complex messages to parents and also undermines breast feeding. In Ireland, breast feeding rates are particularly low at ~50%[(12)], so it was critical that policy in Ireland did not

undermine breast feeding in turn reducing breast feeding rates even more as this would have a profound effect on infant health. Therefore, the approach in Ireland was to use a low dose vitamin D only supplement for all babies, whether breast fed or formula fed[(1)].

III. National policy on vitamin D supplementation

Most countries have a vitamin D supplementation policy in place for infants. In Ireland there is a National supplementation policy[(1)] in place. This policy recommends that all infants living in Ireland are given a daily vitamin D only supplement (containing 5µg vitamin D), regardless of whether breast fed or formula fed. Although with this approach, breastfed babies would not be getting as much vitamin D as those who are formula fed, breastfed babies would be getting sufficient vitamin D to prevent deficiency, whilst at the same time they would be gaining the enormous health benefits derived from breastfeeding.

IV. The need for specific criteria defining 5µg vitamin D food supplements suitable for infants

Since some infants are not formula fed they are receiving very little amounts of vitamin D from breast milk. Therefore breast-fed infants need higher amounts of vitamin D than formula fed infants. The amount of vitamin D provided by formula is also important when considering the amount of vitamin D provided by a supplement for infants.

According to EU guidance[(4)] on tolerances around labelled values, the measured amount of the vitamin must be no more than 20% below or 50% above the labelled value. However, in order to ensure that infants in Ireland are not receiving too much vitamin D a much tighter upper tolerance level of 20% is needed. In order for a food business to have their food supplement listed as being suitable for providing 5µg vitamin D (only) to infants in Ireland in line with the National supplementation policy, the amount of vitamin D provided by the product must fall within the tighter tolerance range (i.e. -20%, +20%).

APPENDIX II – BATCH ANALYSIS MONITORING FORM

A Batch Analysis Monitoring Form needs to be submitted at each application. This form will provide a summary of batch analysis carried out by the applicant to ensure the tolerance around 5µg vitamin D is met.

Example of tabulated summary of batch analysis:

Product Name	**Manufacturer name and address**	**Distributor name and address**	**Lot number**	**Manufacturing date**	**Batch size**	**Pack type/size**	**Best before date**	**Recommended daily dose** (e.g. no. of drops/sprays or measured syringe etc.)	**Amount of vitamin D provided in recommended daily dose**	**Vitamin D assay**	**Certification of Analysis attached**

Note: *This form should be submitted at initial application and when making subsequent applications i.e. if changes have been made to a product.*

APPENDIX III - ABOUT THE WORKING GROUP

The Vitamin D Infant Supplement Working Group members included experts in the area of vitamin D infant nutrition, food law enforcement, public health services and food supplement industry stakeholders[†††].

Members of the Vitamin D Infant Supplement Working Group:

- Prof Mary Flynn (Chair) (FSAI)
- Dr Judith O' Connor (FSAI)
- Ms Emer O'Reilly (FSAI)
- Ms Oonagh Lyons (FSAI)
- Dr Teresa Bennett (Health Promotion & Improvement, HSE)
- Prof Malachi McKenna (St. Vincent's University Hospital & UCD)
- Ms Sinead Kilcommins (Environmental Health Service, HSE)
- Mr Gerry Finn (Beeline Healthcare)
- Mr John Spain (Sona)
- Mr Ohan Yergainharsian (IHTA Representative)
- Ms Sarah Thorn (Kora Healthcare)
- Ms Fiona Stack (Cork Public Analyst Laboratory)
- Mr Fred Davidson (Cork Public Analyst Laboratory)

[†††] Food businesses that had notified infant vitamin D food supplements to the FSAI in the past were contacted and invited to take part in the Working Group

APPENDIX IV – TERMS OF REFERENCE

DRAFT Terms of Reference

Membership of the Vitamin D Infant Supplement Working Group:

Membership of the Vitamin D Infant Supplement Working Group is comprised of experts in the area of vitamin D infant nutrition, food law enforcement, public health services and stakeholders. All members have the knowledge and experience required to assist the FSAI in compiling a Guidance Note for Food Supplement Industry Stakeholders on vitamin D supplements deemed suitable for providing infants with 5µg of vitamin D daily in accordance with National policy in Ireland. The main outcome of this work will be the maintenance of a list of vitamin D food supplement products currently deemed suitable for providing infants with 5µg of vitamin D daily in accordance with National policy in Ireland.

Remit:

The remit of the Working Group is (1) to develop a Guidance Note for Food Supplement Industry Stakeholders on vitamin D supplements deemed suitable for providing infants with 5µg of vitamin D daily in accordance with National policy and (2) initiation and maintenance of a list of vitamin D food supplement products currently deemed suitable for providing infants with 5µg of vitamin D daily in accordance with National policy in Ireland and (3) drafting a dissemination plan on the Guidance Note.

The Guidance Note will:

1. Refer to the legal requirements which must be met to market food supplements in Ireland.
2. Outline the safety issues regarding vitamin D food supplements for infants (i.e. the need to consider other sources of vitamin D in the infant's diet).
3. Provide specification criteria for vitamin D supplements which can be listed as suitable for infants
4. Outline monitoring requirements for the applicant of the listed products to ensure the product meets the specification criteria in order to remain listed
5. Specify action that will be taken when the results of monitoring do not meet with the specification criteria.

The list of vitamin D supplements deemed suitable for providing infants with 5µg of vitamin D daily in accordance with National policy as well as the Guidance Note will be available on the FSAI website.

Meetings:

Physical meetings will take place in FSAI with the option for teleconference. Work will also be carried out electronically.

Confidentiality:

The Food Safety Authority of Ireland will endeavour to maintain the confidentiality of any correspondence marked confidential within its obligations under the Freedom of Information Act.

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