

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
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World Health  
Organization

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Agenda Item 4a

NFSDU/40 CRD 6

Original language only

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Fortieth Session

Berlin, Germany  
26 – 30 November 2018

### DRAFT REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA: ESSENTIAL COMPOSITION REQUIREMENTS Comments at Step 6

*Comments of ISDI*

#### ISDI – International Special Dietary Foods Industries

#### [Section B: for \[Name of product\] for young children](#)

#### [Carbohydrates and Vitamin D<sub>3</sub>](#)

##### Outline of this CRD

- A. Carbohydrates and sugars, [Name of product] for young children
- B. Vitamin D, [Name of product] for young children

#### [A. Carbohydrates and sugars, \[Name of product\] for young children](#)

#### CCNFSDU PROPOSED WORDING FOR CARBOHYDRATE REQUIREMENT IN [NAME OF PRODUCT] FOR YOUNG CHILDREN

Reference: [REP18/NFSDU](#) Appendix II, Section B, 3.1.3 c) footnote 4

##### c) Carbohydrates

###### Available carbohydrates <sup>4)</sup>

| Unit        | Minimum | Maximum <sup>5)</sup> | GUL |
|-------------|---------|-----------------------|-----|
| g /100 kcal | -       | 12.5                  | -   |
| g /100 kJ   | -       | 3.0                   | -   |

4) [Lactose should be the preferred carbohydrates in [name of product] based on milk protein. For products not based on milk protein, carbohydrate sources (like starch) that have no contribution to the sweet taste should be preferred.

Mono- and disaccharides, other than lactose, either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means, should not exceed 2.5 g/100kcal (0.60 g/100kJ) of available carbohydrate. National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose or other carbohydrates contributing to the sweet taste of [name of product] should not be added, unless needed as a carbohydrate source. Other non-carbohydrate ingredients should not be added with the purpose of imparting or enhancing a sweet taste. ]

**EXECUTIVE SUMMARY:**

ISDI strongly support the efforts by CCNFSDU to establish appropriate requirements for carbohydrates and sugars in the revised standard for [Name of product] for young children. ISDI notes that no specific requirements are established for carbohydrates and sugars in the current Codex Standard for Follow-up formula and thus the revised standard will introduce considerable change.

The proposed text (footnote 4) remains in square brackets and ISDI welcomes further discussion at CCNFSDU40. In particular, ISDI respectfully reminds the committee that:

- All requirements must be based on sound science
- All requirements must be non-subjective
- All requirements must be enforceable

These principles are critical to ensure that trade issues will not ensue, once the standard is transposed into local legislation.

Further to the above points:

- ISDI supports the establishment of a maximum level of 2.5g/100kcal for mono and di-saccharides other than lactose in [Name of product] for young children. ISDI believes that this maximum coupled with a maximum level for available carbohydrates, meet the principles highlighted above. These requirements will result in a product with a carbohydrate/sugar profile superior to many foods consumed by this age profile, as part of their diversified diet.
- ISDI notes that the addition of sucrose and fructose, may be needed in certain formulas for example those based on plant protein, hydrolysed protein or lactose free.
- ISDI does not support any reference to ‘sweet taste’ in footnote 4, as the concept of ‘sweet taste’ is complex, subjective, and non-enforceable.

Further details are provided below along with some general background information on carbohydrates in section A.

**1. Overview of CCNFSDU proposal for carbohydrates in “[Name of the product] for young children**

Details of the current CCNFSDU proposal for carbohydrates in ‘[name of product] for young children’ are broken down in Table below. (Please note that while many of the proposals are logical; the proposal for ‘sweetness’ is challenging because it is not enforceable and therefore it should not be included in a Codex standard. Further details are provided in point 2 below).

**Table:** Breakdown of the current CCNFSDU proposal for carbohydrates in ‘[name of product] for young children’

| Ref | Requirement                          | Proposal  | Commentary  |
|-----|--------------------------------------|---|---|
| 1   | Maximum for ‘available carbohydrate’ | Maximum for ‘available carbohydrate’ of 12.5g/100kcal<br><br>If the protein level is below 3.0 g/100 kcal, a carbohydrate maximum of up to 14 g/100 kcal may be permitted by competent national and/or regional authorities | <b>THIS PROPOSAL WOULD LEAD TO A NEW REQUIREMENT</b><br><br>The current codex standard for FuF does not establish specific levels for carbohydrates <sup>1</sup><br><br>The max proposed for ‘available carbohydrates’ (coupled with the levels proposed for protein and fat) ensure that the energy balance from all macro-nutrients is aligned with recommendations from recognised authoritative scientific bodies for the age group 1-3 years. Codex defines ‘available carbohydrate’ as ‘dietary carbohydrate excluding dietary fibre’ <sup>2</sup><br><br><b><u>ISDI SUPPORTS THIS PROPOSAL</u></b> |

<sup>1</sup> The current codex standard for follow-up formula (CODEX STAN 156-1987) specifies levels for energy, protein and fat. The carbohydrate level is based on the ‘residual energy’ once the protein and fat levels have been determined

<sup>2</sup> Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985)

|   |   |   |  |
|---|---|---|--|
| 2 | Lactose                                     | Lactose should be the preferred carbohydrates in [name of product] based on milk protein  | <p><b>THIS PROPOSAL WOULD LEAD TO A NEW REQUIREMENT</b></p> <p>The current codex standard for FuF does not specify a preference for lactose</p> <p><b><u>ISDI SUPPORTS THIS PROPOSAL</u></b></p>   |
| 3 | Products not based on milk protein          | For products not based on milk protein, carbohydrate sources (like starch) that have no contribution to the sweet taste should be preferred.  | <p><b>THIS PROPOSAL WOULD LEAD TO A NEW REQUIREMENT</b></p> <p>The current codex standard for FuF does not specify a preference for carbohydrate sources in products not based on milk protein.</p> <p><b>ISDI DOES NOT SUPPORT THIS PROPOSAL</b></p> <p><b>Rationale</b></p> <ul style="list-style-type: none"> <li>-The use of starch as the sole carbohydrate source in such products is not technically feasible.</li> <li>- As a result, the increased product viscosity of the products is likely not being accepted by the young child due to the texture</li> <li>-A product with high amount of starch, may bring some digestive discomfort to the young child</li> </ul> |
| 4 | Sucrose and/or fructose                     | Sucrose and/or fructose should not be added, unless needed as a carbohydrate source   | <p><b>THIS PROPOSAL WOULD LEAD TO A NEW REQUIREMENT</b></p> <p>The current codex standard for FuF does not mention sucrose and fructose</p> <p><b><u>ISDI SUPPORTS THIS PROPOSAL IF FURTHER CLARIFICATION IS PROVIDED</u></b></p> <p>Sucrose and/or fructose may be needed in certain formulas for example those based on plant protein, hydrolysed protein or lactose free.</p> <p><b>Rationale</b></p> <p>ISDI propose this additional wording for palatability reason.</p> <p>ISDI considers whether it would be more meaningful to include palatability in the footnote.</p>   |
| 5 | Mono- and disaccharides, other than lactose | Mono- and disaccharides, other than lactose, either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means, should not exceed 2.5 g/100kcal of available carbohydrate. National and/or regional authorities may limit this level to 1.25 g/100 kcal. | <p><b>THIS PROPOSAL WOULD LEAD TO A NEW REQUIREMENT</b></p> <p>The current codex standard for FuF does not specify levels for 'mono- and disaccharides, other than lactose'</p>  |

|   |             |   |   |
|---|-------------|---|---|
|   |             |   | <p><b><u>ISDI SUPPORTS THE PROPOSED RESTRICTION ON MONO- AND DISACCHARIDES OTHER THAN LACTOSE AT 2.5 g/100 KCAL</u></b></p> <p>At this maximum level, ‘mono and di saccharides other than lactose’ would contribute 10% of the products total energy. This aligns with the WHO (2015) guideline which strongly recommends the adults and children reduce their daily intake of free sugars to less than 10% of their total energy intake. However, it is important to point out that that the WHO guideline is ‘dietary-based’ i.e. it applies to the whole diet and not to specific products.</p> <p><b>ISDI DOES NOT SUPPORT THE PROPOSED RESTRICTION ON MONO- AND DISACCHARIDES OTHER THAN LACTOSE AT 1.25g/100 KCAL</b></p> <p>This restriction is inspired by the WHO guideline to limit free sugars to less than 5% of total energy intake, which is a conditional recommendation. In addition, and as stated above, the recommendation is intended to apply to the total diet rather than individual products.</p> |
| 6 | Sweet taste | <ul style="list-style-type: none"> <li>▪ For products not based on milk protein, carbohydrate sources (like starch) that have no contribution to the <b>sweet taste</b> should be preferred.</li> <li>▪ Carbohydrates contributing to the <b>sweet taste</b> of [name of product] should not be added, unless needed as a carbohydrate source.</li> <li>▪ Other non-carbohydrate ingredients should not be added with the purpose of imparting or enhancing a <b>sweet taste</b></li> </ul> | <p><b>THIS PROPOSAL WOULD LEAD TO A NEW REQUIREMENT</b></p> <p>The current codex standard for FuF does not reference ‘sweet taste’</p> <p><b>ISDI DOES NOT SUPPORT THIS PROPOSAL AS ‘SWEETNESS’ IS SUBJECTIVE AND IS NOT ENFORCEABLE (SEE POINT 2 BELOW FORMORE DETAILS)</b></p>  |

## 2. Concern regarding the introduction of ‘sweet taste’ into the revised codex standard

The concept of ‘sweet taste’ is complex, subjective, and non-enforceable. More specifically:

- The only methods currently available to measure ‘sweetness’ require human sensory panels. Such methods are not appropriate for compliance/enforcement purposes. They are highly dependent on factors including food matrix, blood sugar level at time of consumption and temperature of the food ingested. The possibility of establishing sensory panels for the targeted population (1-3 year olds) is also questionable.
- From an analytical perspective, it would be very difficult to develop/validate an objective method (appropriate for compliance/enforcement purposes) to measure sweetness. Complicating this analysis would be the need to calibrate any instrumental or immunological based assay back to a human tester.
- Following the [EFSA public consultation on a draft protocol for the Scientific Opinion on dietary sugars](#), EFSA has noted that “Sweet taste”, and the development of taste and food preferences in infants and children, are not endpoints for the assessment.

Furthermore, regarding the perceived relationship between ‘sweet taste exposure in early life’ and ‘sweet preference in later life’ it is important to note that:

- Sweet taste perception and preference is complex and multifactorial. Much of sweet taste perception and preference is genetically determined.
- There is no definitive evidence that 'sweet taste exposure in early life' leads to 'sweet preference in later life'. Such a relationship is equivocal.

Considering these points, all reference to 'sweet taste' (reference 5 in Table 2) should be removed from the Codex proposal and ISDI strongly supports the efforts by CCFSDU to restrict the level of mono- and disaccharides from all sources other than lactose at 2.5 g/100 kcal.

### 3. Additional comments from ISDI on proposed footnote 4

ISDI would also like to note the following comments on the text proposal:

- The text, "...either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means," is a very wordy way of stating 'total amount present'. **ISDI recommends that the sentence is simplified and this wording is deleted accordingly.**
- The following sentence, "National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ)," should be deleted. **ISDI doesn't support a restriction on mono- and disaccharides other than lactose at 1.25g/100 kcal.** This restriction is inspired by the WHO guideline to limit free sugars to less than 5% of total energy intake, which is a conditional recommendation. In addition, and as stated above, the recommendation is intended to apply to the total diet rather than individual products.
- To achieve palatability, sucrose and/or fructose may be needed in certain formulas for example those based on plant protein, hydrolysed protein or lactose free.

**ISDI reiterates that all requirements incorporated into the revised codex standard must be enforceable**, once the codex standard is transposed into regional /national law. ISDI considers, in that perspective, that the limits set for 'sugars (mono- and disaccharides other than lactose)' and 'available carbohydrates' are clear criteria. They are sufficient and appropriate for public health and are enforceable as they can be analytically measured.

### 4. ISDI counter-proposal for footnote 4

#### c) Carbohydrates

##### Available carbohydrates<sup>4)</sup>

| Unit        | Minimum | Maximum <sup>5)</sup> | GUL |
|-------------|---------|-----------------------|-----|
| g /100 kcal | -       | 12.5                  | -   |
| g /100 kJ   | -       | 3.0                   | -   |

4) [Lactose should be the preferred carbohydrates in [name of product] based on milk protein. ~~For products not based on milk protein, carbohydrate sources (like starch) that have no contribution to the sweet taste should be preferred.~~

~~Mono- and disaccharides, other than lactose, either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means, should not exceed 2.5 g/100kcal (0.60 g/100kJ). National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose or other carbohydrates contributing to the sweet taste of [name of product] should not be added, unless needed as a carbohydrate source in products such as [Name of Product] based on plant protein, hydrolysed protein or lactose free. Other non-carbohydrate ingredients should not be added with the purpose of imparting or enhancing a sweet taste.~~

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#### c) Carbohydrates

##### Available carbohydrates<sup>4)</sup>

| Unit        | Minimum | Maximum <sup>5)</sup> | GUL |
|-------------|---------|-----------------------|-----|
| g /100 kcal | -       | 12.5                  | -   |
| g /100 kJ   | -       | 3.0                   | -   |

4) [Lactose should be the preferred carbohydrates in [name of product] based on milk protein.

Mono- and disaccharides, other than lactose should not exceed 2.5 g/100kcal (0.60 g/100kJ). Sucrose and/or fructose should not be added, unless needed as a carbohydrate source **in products such as [Name of Product] based on plant protein, hydrolysed protein or lactose free**.

## Section A

### GENERAL BACKGROUND INFORMATION ON CARBOHYDRATES

#### 1. Brief background on carbohydrates

Carbohydrates are a component of food that supply energy to the body through calories. Along with the other macro-nutrients (proteins and fats), they provide the energy needed in our daily lives. This includes the energy needed for normal body functions such as heartbeat, breathing and digestion and the energy needed for physical activity and exercise.

#### 2. Carbohydrate terminology

There are many ways to describe carbohydrates, e.g. by size (**mono-, di-, oligo- or poly-saccharide**) or by type (**sugars, fibre, starch**). This is captured in Table 1:

**Table 1: A focus on carbohydrates**

| Size              | Description  | Examples*  | Type                                  |
|-------------------|--|--|---------------------------------------|
| Mono-saccharides  | A <b>monosaccharide</b> is the most basic unit. It is the building block of di-, oligo- and poly-saccharides | <ul style="list-style-type: none"> <li>▪ Glucose (aka Dextrose)</li> <li>▪ Fructose</li> <li>▪ Galactose</li> </ul>  | Sugars <sup>(2)</sup>                 |
| Di-saccharides    | A <b>disaccharide</b> is composed of 2 monosaccharides bound together  | <ul style="list-style-type: none"> <li>▪ Lactose (i.e. glucose + galactose)</li> <li>▪ Sucrose (i.e. glucose + fructose)</li> <li>▪ Maltose (i.e. glucose + glucose)</li> </ul>  |                                       |
| Oligo-saccharides | An <b>oligosaccharide</b> is composed of 3-9 monosaccharides bound together                                  | <ul style="list-style-type: none"> <li>▪ Maltodextrin (i.e. polymer of glucose units)</li> <li>▪ Glucose syrup (i.e. polymer of glucose units)</li> </ul>  | Hydrolysates of starch <sup>(1)</sup> |
|                   |  | <ul style="list-style-type: none"> <li>▪ Galacto-oligosaccharides, GOS (i.e. Polymer of galactose units with a terminal glucose unit)</li> <li>▪ Fructo-oligosaccharides, FOS (i.e. Polymer of fructose units with a terminal glucose unit)</li> </ul> | Fibre <sup>(3)</sup>                  |
| Poly-saccharides  | A <b>polysaccharide</b> is composed of more than 10 monosaccharides bound together                           | <ul style="list-style-type: none"> <li>▪ Starch (i.e. Polymer of several thousand glucose units bound together)</li> </ul>   | Starch <sup>(1)</sup>                 |
|                   |  | <ul style="list-style-type: none"> <li>▪ Maltodextrin (i.e. polymer of glucose units)</li> </ul>   | Hydrolysates of starch <sup>(1)</sup> |
|                   |  | <ul style="list-style-type: none"> <li>▪ Dietary fibre</li> </ul>  | Fibre <sup>(3)</sup>                  |

\*These examples are relevant to discussions on [name of product] for young children

<sup>(1)</sup> Starch (found in plants such as wheat, corn) is a *polysaccharide* consisting of several thousand **glucose** units bound together. It can be hydrolysed (broken down) to form:

Maltodextrin: Mixture of glucose chains that vary from 3 to 17 units long (*oligo- or polysaccharide*)

Glucose syrups: Mixture of glucose chains that vary from 3 to 9 units long (*oligo-saccharide*)

Maltose: Di-saccharide consisting of 2 glucose units

Glucose: Mono-saccharide

- (2) The Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985) defines sugars as ‘*all mono-saccharides and di-saccharides present in food*’

The Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985) outlines several criteria to help define ‘dietary fibre’. One of these criteria relate to polymer length. The decision on whether to include carbohydrate polymers between 3 and 9 monomeric units, in the definition of dietary fibre, is left to national authorities. The Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985) define ‘available carbohydrate’ as ‘dietary carbohydrate excluding dietary fibre’. This is because dietary fibre is not digested in the human small intestine (It passes into the large intestine where it is partially or fully fermented).

### 3. Carbohydrates in the diet of young children (1-3 years)

Carbohydrates are an essential part of the diet of young children. They are found in many foods consumed as part of their diversified diet. For example, sugars such as lactose and fructose are found in milk and fruit respectively. Starch is found in potatoes. These carbohydrates are broken down by the body and are used for energy, growth and development. A diversified diet also contains fibre which is essential for good digestive health. Nutritional guidelines have been developed by many scientific bodies to specify the amount of energy which should come from carbohydrates and the other macro-nutrients (protein and fat). These recommendations, along with those for micro-nutrients, are used by many regulatory authorities across the globe to define the compositional requirements for follow-up formula for older infant and young children.

#### B. Vitamin D<sub>3</sub>, [Name of product] for young children

#### PROPOSAL FOR VITAMIN D REQUIREMENT IN [NAME OF PRODUCT] FOR YOUNG CHILDREN

Reference: [REP18/NFSDU](#) Appendix II, Section B, 3.1.3 d) **vitamin D<sub>3</sub>**

[Vitamin D<sub>3</sub><sup>9)</sup>

| Unit                        | Minimum | Maximum | GUL |
|-----------------------------|---------|---------|-----|
| µg <sup>10)</sup> /100 kcal | [1.5]   | [4.5]   | -   |
| µg <sup>10)</sup> /100 kJ   | [0.36]  | [1.08]  | -   |

<sup>9)</sup> Competent national and/or regional authorities may deviate from the conditions as appropriate for the nutritional needs of their population.]

<sup>10)</sup> Calciferol. 1 µg calciferol = 40 IU vitamin D.

#### EXECUTIVE SUMMARY:

ISDI supports the mandatory addition of vitamin D to [name of product] for young children at a minimum level of 1.5 µg /100 kcal and a maximum level of 4.5 µg/100 kcal.

Vitamin D deficiency is recognized as a public health concern for young children (Suthutvoravut et al, 2015). Inadequate vitamin D dietary intakes are observed in young children worldwide. Low vitamin D status is a global concern, even in regions with higher sunlight exposure.

Daily consumption of 300-500ml of [name of product] for young children, with a vitamin D level up to 4,5 µg/100 kcal, as part of a diversified diet, will result in food intake which better covers the vitamin D needs of young children. And, importantly, this improved intake of vitamin D will be achieved without exceeding the recommended daily UL for vitamin D specified by EFSA of 50 µg/day.

ISDI supports the use of both vitamin D<sub>3</sub> and vitamin D<sub>2</sub> in name of product] for young children and that a reference to vitamin D is made in the text instead of vitamin D<sub>3</sub>.

#### 1. Importance of Vitamin D

Vitamin D plays a crucial role in the maintenance of normal blood levels of calcium and phosphate, which are needed for bone mineralization, muscle and cardiovascular function (IOM 2011, FAO 204). In addition, vitamin D positively influences calcium absorption and contributes to normal immune function (WHO/FAO 2004).

Vitamin D deficiency is common in children worldwide. The prevalence of vitamin D deficiency increases with age as the compliance with recommended supplementation decreases (Kensarah, 2015, Hintzpeter et al, 2008). High prevalence of vitamin D deficiency and insufficiency has been documented in Europe, China, India, Middle East and South America (Holick 2017). In some countries, up to 95% of children are diagnosed as vitamin D insufficient (vitamin D status < 50 nmol/L) and 73% as vitamin D deficient (vitamin D status < 30 nmol/L) (Palacios 2014).

In tropical or subtropical climates, there is generally abundant exposure to sunlight, but vitamin D deficiency may arise in association with risk factors such as darker skin pigmentation, atmospheric pollution, and covering skin (Baroncelli 2008, Elder 2014, Green 2015, Trilok Kumar 2015).

Studies on vitamin D levels in young children in sub-Saharan Africa indicates that despite the high level of sunshine, both vitamin D deficiency and vitamin D dependent rickets are an issue in young children: a study from Botswana found that nearly 20% of children below 2 years of age were vitamin D deficient (Ludmir 2016). Nutritional rickets remains a serious public health issue, and while in West Africa, its main cause seems to be inadequate calcium intakes, vitamin D deficiency plays an important role in countries such as Kenya, Congo and Malawi (Creo 2017) and low vitamin D levels seem to be an independent risk factor even in a sub-Saharan context (Jones, 2018).

**2. Recommended daily intake and upper level intake**

US Institute of Medicine (IOM 2011) and EFSA (EFSA 2016) set a dietary reference value for children 1-3 years when endogenous synthesis is minimal at 15 µg/day. Other organizations have lower (WHO 2004: 5 µg/day) or higher (DACH 2015: 20 µg/day) recommended intake levels.

The upper level intake (UL) for vitamin D increases from infancy to childhood. EFSA proposed a UL of **50 µg/day** for children above 1 year (1-10 years). In 2011, taking a cautious and prudent approach, IOM proposed to increase the UL for children aged 1-3 years from 50 µg/day (IOM 1997) to 62.5 µg/day (IOM 2011).

**3. Real daily intake**

Very few foods naturally contain vitamin D. Various nutritional surveys demonstrate inadequately low intakes of vitamin D in a large spectrum of countries.

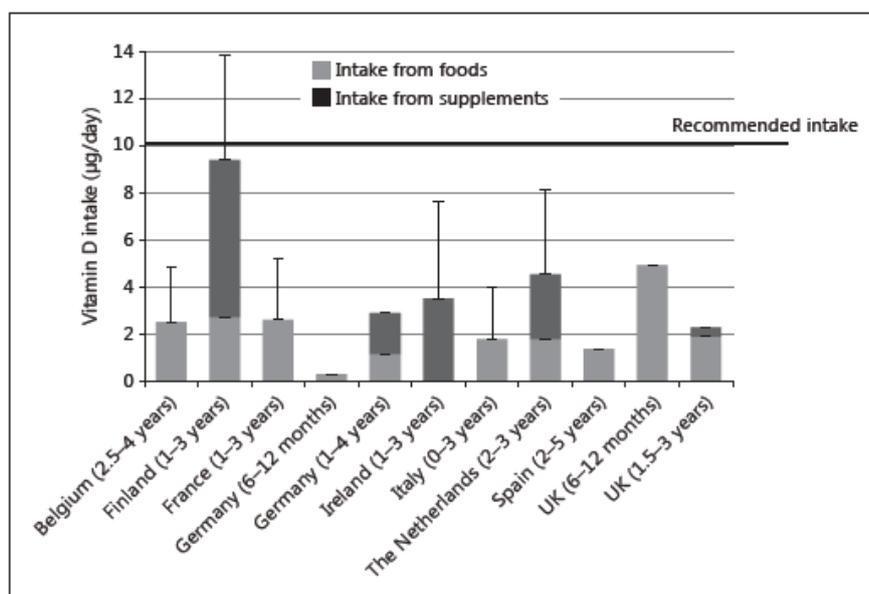


Figure 1 Vitamin D intake of older infants and young children in European countries compared to Nordic recommendation (Alles et al., 2014)

Low dietary intakes of vitamin D are observed in other geographies. The Malaysian SEANUTS study reported a daily vitamin D intake of 6.3 µg and indicated that 37% of young children (1 to 3.9 years) did not achieve Malaysian recommended Vitamin D intakes (Poh 2013). A survey completed in Western Saudi Arabia showed inadequate vitamin D intake in 1-3 years toddlers (Kensarah 2015).

**4. Intake from [name of product] for young children**

[Name of product] for young children with a vitamin D content up to 4,5 µg/100 kcal and assuming 300 ml recommended daily intake would add up to 8,1-9,5 µg of vitamin D/day, and intake of 500 ml up to 15,8 µg/day.

| 4,5 µg/100 kcal |                 |        |
|-----------------|-----------------|--------|
|                 | ml daily intake |        |
| kcal/100 ml     | 300 ml          | 500 ml |

|    |        |         |
|----|--------|---------|
| 60 | 8,1 µg | 13,5 µg |
| 70 | 9,5 µg | 15,8 µg |

A simulation based on the intake data from the UK and a [name of product] for young children with a Vitamin D level of 4,5 µg/100 kcal confirms that the UL is never reached (Eussen et al., 2015)

Even when high intake of vitamin D from food is considered with the recommended supplementation of 10 µg/d (Braegger 2013), and consumption of 500 ml [name of product] for young children with a vitamin D level of 4,5 µg/100 kcal, it would not exceed the UL given by EFSA 50 µg/d) or IOM (62,5 µg/d). This is demonstrated in the following tables.

|                             | High intake of Vitamin D |             |             |                  |
|-----------------------------|--------------------------|-------------|-------------|------------------|
| Data from EFSA , 2012       | Denmark P 95             | Greece P 90 | Dutch P 90  | Finland P 75     |
|                             | 1-3 years                | 1-5 years   | 1,5 years   | 2-3 years, girls |
| Intake from food (µg/d)     | 2,4                      | 11,9        | 8,1         | 12,6             |
| Supplementation (10 µg/d)   | 10                       | 10          | 10          | 10               |
| 500 ml with 4,5 µg/100 kcal | 15,8                     | 15,8        | 15,8        | 15,8             |
|                             |                          |             |             |                  |
| <b>Total intake (µg/d)</b>  | <b>28,2</b>              | <b>37,7</b> | <b>33,9</b> | <b>38,4</b>      |

|                             | Mean intake of Vitamin D |             |               |                |
|-----------------------------|--------------------------|-------------|---------------|----------------|
| Data from EFSA , 2012       | Denmark                  | Greece      | UK            | Finland        |
|                             | 1-3 years, boys          | 1-5 years   | 1,5 - 3 years | 2 years, girls |
| Intake from food (µg/d)     | 1,7                      | 5,6         | 2,3           | 9              |
| Supplementation (10 µg/d)   | 10                       | 10          | 10            | 10             |
| 500 ml with 4,5 µg/100 kcal | 15,8                     | 15,8        | 15,8          | 15,8           |
|                             |                          |             |               |                |
| <b>Total intake (µg/d)</b>  | <b>27,5</b>              | <b>31,4</b> | <b>28,1</b>   | <b>34,8</b>    |

### Vitamin D versus Vitamin D3

ISDI would like to highlight an inconsistency with the proposal to list **Vitamin D3** rather than **Vitamin D** as a mandatory nutrient in (*Name of product*) for young children. As highlighted in the table below, **Vitamin D** is:

- Listed as a mandatory nutrient in Codex Standard 156-1987
- Proposed as a mandatory nutrient in Follow up formula for older infants

| Standard  | Age group   | Vitamin D / D3 |
|---|---|----------------|
| <b>CODEX STAN 156-1987</b>                      | 6-36 months   | Vitamin D      |
| <b>Proposed Revision of CODEX STAN 156-1987</b> | Follow-up formula for older infants (6-12 months)   | Vitamin D      |
|   | (Name of product) for young children (12-36 months) | Vitamin D3     |

The two most prominent forms of **vitamin D** are:

- **Vitamin D3** (cholecalciferol) – derived from animal sources
- **Vitamin D2** (ergocalciferol) – derived from plant sources

Establishment of a mandatory criterion for Vitamin D3 in (*Name of product*) for young children will create problems for vegetarians.

This challenge would be resolved by the establishment of a mandatory criterion for **Vitamin D** in (Name of product) for young children. It would also resolve the issue of inconsistency.

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