CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 4a **CX/NFSDU 18/40/4-Add.1**

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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 Egypt, the European Union, Singapore, United States of America and Vietnam

EGYPT

Section A: Essential composition of Follow UP formula for Older Infants

Egypt agrees with Section A: Essential composition of Follow UP formula for Older Infants at step 6

Section B: Essential composition of Follow UP formula for [Name OF Product] For Young Children

1- Egypt agrees with Section B: Essential composition of Follow UP formula for [Name OF Product] For Young Children at step 6.

2- Egypt supports the following proposal for Vitamin D and to remove the brackets:

Vitamin D_3[9)]

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

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

10) Calciferol. 1 µg calciferol = 40 IU vitamin D.

EUROPEAN UNION

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

As regards footnote 1 the EU would like to kindly note that the associated text on GUL seems to be missing. The text used in the footnote of 3.1.3 in Section B could be taken.

The EU would have a small editorial comment on footnote 8: the product name should be amended from 'infant formulae' to 'Follow-up formula(e) (for older infants)'.

The EU would like to kindly note that the wording of footnote 10 could be aligned with the similar footnote found in the Codex Standard for infant formula and footnote 8 of Section B of this Standard by adding the prefix "all" to trans retinol as follows:

*1 µg RE = 3.33 IU Vitamin A = 1 µg **all-**trans retinol.*

The EU would like to kindly note that a small editorial change proposed below to footnote 20 would improve the wording and would ensure consistency with that of other similar footnotes in the Standard (e.g. footnote 17):

*For Follow-up formula based on soy protein isolate a minimum value of 0.75 mg/100 kcal (0.18 mg/100 kJ) **applies.***

SECTION B: [NAME OF PRODUCT] FOR YOUNG CHILDREN

The EU supports the wording of the first 2 sentences proposed for footnote 4 (the first paragraph of the footnote). The "s" at the end of the word "carbohydrates" should be deleted.

With respect to the second paragraph of footnote 4, the EU is in favour of the lower level indicated, 1.25 g/100 kcal (0.30 g/100 kJ). If additionally an option for national/and or regional authorities to grant a higher level of 2.5 g/100 kcal (0.60 g/100kJ) is stated the EU could support such a solution to accommodate different views on the matter. This part of the footnote is limiting sugars content other than lactose, in line with WHO recommendations. The EU supports the third and fourth sentence of the second paragraph as they address the concern that products that were identified by the European Food Safety Authority as not being essential in the diet of young children could negatively influence taste preferences of young children. It is important to consider that potentially such products could be consumed over a period of 2 years on a daily basis and during a period of life where taste preferences are strongly influenced. In order to cover all sources of fructose and sucrose and to be in line with the wording for mono- and disaccharides, The EU proposes the wording:

Sucrose and/or fructose or other carbohydrates contributing to the sweet taste of [name of product] should not be added **as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means**, unless needed as a carbohydrate source.

Furthermore, the EU proposes an alternative, more comprehensive wording to replace the last sentence of footnote 4:

~~**Other non-carbohydrate il**~~Ingredients should not be added with the purpose of imparting or enhancing a sweet taste.]

Text Proposal:

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

The EU continues to support a minimum level of 1 µg/100 kcal and a maximum level of 3 µg/100 kcal, which align with the values agreed for Follow-Up Formula for older infants. Such values would also ensure consistency with the pragmatic approach followed in the Committee for the mandatory addition of other micronutrients whose intakes are widely inadequate in the diet of young children i.e. simply to refer to the values agreed for Follow-Up Formula for older infants.

SINGAPORE

Codex's proposed draft	Singapore's comments	Rationale
Sodium chloride should not be added to [name of the product] for young children.	Singapore understands that the rationale to prohibit the addition of sodium chloride was to increase the nutritional safety of the products without impacting the inherent levels of sodium in cow's milk. The prohibition on the use of sodium chloride coupled with the absence of a maximum level for total sodium (i.e. inherent and added sodium), do not protect the nutritional integrity of the product (*EFSA, 2017*). If high sodium intake is a concern, it is more meaningful to set a	Sodium chloride is a common source for sodium and chloride, and may be present in the product as a sub-ingredient. If high sodium intake is a concern, it is more meaningful to set a limit for sodium instead of prohibiting the addition of sodium chloride, which is only one of the source of sodium. Singapore suggests adopting the limit set in

<table>
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<td>limit for sodium instead of prohibiting the addition of sodium chloride, which is only one of the sources of sodium. Instead of prohibiting the use of sodium chloride in formula for young children, Singapore would like to propose that in such products, the sodium level from all sources (i.e. inherent & added) must not exceed the maximum level specified in CODEX STAN 156-1987, i.e. 85 mg/100kcal.
Reference: EFSA. 2017. Draft Scientific Opinion. Dietary Reference Values for Sodium</td>
<td>the current Codex Standard for Follow-up Formula (CODEX STAN 156-1987), i.e. “If sodium salts are added to the product, then the maximum sodium level should be 85 mg/100kcal."</td>
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Available carbohydrates[4)]
*
<table>
<tr><th>[4)] Unit</th><th>Minimum</th><th>Maximum[5)]</th><th>GUL</th></tr>
<tr><td>g /100 kcal</td><td>-</td><td>12.5</td><td>-</td></tr>
<tr><td>g /100 kJ</td><td>-</td><td>3.0</td><td>-</td></tr>
</table>
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.</td>
<td>Singapore would like to propose the following edits to the footnote 4:
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~~ do not impart a sweet taste to the product 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.~~ The total content of mono- and disaccharides, other than lactose, should not exceed 2.5g/100kcal (0.60g/100kJ) of available carbohydrate. National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ) of available carbohydrate. 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.]</td>
<td>Industry feedback generally indicate that starch is not an ideal replacer due to its characteristic.

The other proposed edits are mainly editorial.</td>
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	Clean copy: 4) Lactose should be the preferred carbohydrates in [name of product] based on milk protein. For products not based on milk protein, carbohydrate sources that do not impart a sweet taste to the product should be preferred. The total content of mono- and disaccharides, other than lactose, should not exceed 2.5g/100kcal (0.60g/100kJ) of available carbohydrate. National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ) of available carbohydrate. 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.	

UNITED STATES OF AMERICA

The United States strongly supports adoption of the essential composition requirements for older infants and young children of the standard to progress the completed work.

The United States, in general, supports adoption of proposed draft essential composition requirements and has specific comments on the following:

- Hydrolyzed Protein for older Infants
- Available Carbohydrates – Sweet taste footnote for older infants and young children
- Vitamin D for young children
- DHA Upper Limit for older infants

<u>Hydrolyzed Protein for older infants</u>

- The United States notes that the protein level in footnote 6 for hydrolyzed protein now appears to be at a lower level found in the Infant Formula Standard. We suggest an edit for clarity to avoid creating a stricter standard for protein in the FUF-Older Infant (FUF-OI) product than that for infant formula. We note that the proposed footnote 6 includes hydrolyzed protein at the same level as non-hydrolysed milk protein (less than 1.8 g/100 kcal) rather than 2.25 g protein/100 kcal. We also consider it important to distinguish partially hydrolyzed proteins that are often used in routine infant formulas from extensively hydrolyzed proteins used for the management of certain food allergies and as an ingredient in products for special medical purposes.
- The United States has previously commented on the importance of protein quality, particularly for the FUF-OI because the amount and quality of the protein in the foods offered for older infants are often limited. We consider the amino acid pattern in human milk to continue to be the appropriate profile for the older infant (6-12 months).
- We continue to consider it appropriate to retain the concept that any hydrolysed protein should be clinically tested for growth, tolerance, and adverse events, unless it has been already evaluated in younger infants. The partial protein hydrolysates used in routine infant formulas are manufactured by different processes, resulting in products which may vary in nutritional adequacy, particularly if the

protein is not a cow milk protein. Further, we also consider clinical evaluation of 1.65-1.8 g protein/100 kcal necessary since there are very limited data available for such products.

- We recommend editing Footnote 6to include the protein gram level for hydrolyzed protein so that the FUF-OI is not a stricter standard than infant formula:

> [Infant formula based on non-hydrolysed milk protein containing less than 1.65-1.8 g protein/ 100 kcal and infant formula based on hydrolysed protein containing less than 2.25 g protein/ 100 kcal should be clinically evaluated]. **We note that oligosaccharides are not listed under optional ingredients under the composition for older infants and suggest it be added.

Available Carbohydrates for older infants and young children

- The United States supports limiting added sugar to foods for children. However, we do not agree with the text proposed under 3.1.3 c) footnote 4. The phrase [and other carbohydrates contributing to the sweet taste] should be deleted. This is not enforceable from a regulatory standpoint. There is no definition or standardized method of measurement for "sweet taste" Inclusion sweet taste" or similar phrases present unresolvable evaluation and enforcement issues. We also note that the amount of carbohydrate as sugar would be constrained by the percentages of the other macronutrients. We suggest the following edits:

> 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.~~
>
> The total content of mono- and disaccharides from all sources, 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 in cow milk-based products. ~~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.]~~

Vitamin D for young children

The United States continues to support the mandatory addition of Vitamin D to the [Product Name] for young children and the proposed levels in the square brackets for the minimum and maximum levels. We note that both forms of vitamin D (D2 and D3) are permitted for infant formula and follow up formula in the list of the permitted forms of nutrients in the *Codex Advisory List of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CAC/GL 10-1979). Therefore, it would be unnecessary and inappropriate to refer to vitamin D3 in the requirements for follow-up formula for older infants (CX/NFSDU 15/37/5) and this reasoning should also apply to [name of product] for young children. Vitamin D is required for calcium absorption and is also involved in maintaining bone mineral homeostasis as well as regulating renal calcium excretion. We also support footnote 9 as it allows for adjustment in the levels of vitamin D.

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

DHA (ARA) as optional ingredients in FUF-OI

The United States supports the addition of DHA as an optional ingredient with levels provided in the Standard because many members indicated that this type of information was needed to support regulations. It is reasonable to provide levels of optional ingredients that have been shown to have a level needed to provide for its physiological effects. If DHA is added, the level at which it is added should be associated with a scientifically supported positive physiological outcome beneficial to the older infant (6-12 months). Further, the addition of DHA and ARA should be considered together so that the level of DHA added in any situation would vary with the addition of ARA in the formula.

The United States continues to support the principle that minimum level of DHA should be set as proposed in footnote 20. The rationale for proposing a fixed minimum level was to avoid the level of DHA/EPA from becoming too low when levels of fatty acids are reduced. We agree with the findings from the European Union (EFSA 2014) and consider a fixed level of DHA at a higher minimum. The range supported by the eWG of 16-20 mg/100 kcals is an appropriate alternative because it is unlikely that infants 6-12 months of age will consume other sources of DHA in their diversified diet. We prefer to take the midpoint of the percentage of fatty acid range (0.4%) and the midpoint of the fat range 5.2g/100kcal to set the minimum level which rounds to 20mg/100kcal.

Footnote 20: If docosahexanoic acid (22:6n-3) is added to follow-up formula, a minimum level of [20 mg/100 kcal (4.75 mg/ 100 kJ)] should be reached, and arachidonic acid (20:4 n-6) contents should reach at least the same concentrations as docosahexaenoic acid. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. Competent nutritional needs of their local population based on the suitability and availability of food sources of DHA in the diversified diet.

VIETNAM

Draft	**Vietnam's proposal**	**Rationale**
3.1.3 Footnote 6 A lower minimum protein level between 1.6 and 1.8 g/100 kcal (0.38 and 0.43 g/100 kJ) in follow-up formula based on non-hydrolysed milk protein can be accepted. Such follow-up formula and follow-up formula based on hydrolysed protein should be evaluated for their safety and suitability and assessed by a competent national and/or regional authority based on clinical evidence.	**Vietnam suggests to change it to:** A lower minimum protein level between 1.6 and 1.8 g/100 kcal (0.38 and 0.43 g/100 kJ) in follow-up formula based on non-hydrolysed milk protein can be accepted. Such follow-up formula should be evaluated for their safety and suitability and assessed by a competent national and/or regional authority based on clinical evidence. Follow-up formula based on hydrolysed protein containing less than 2.25 g protein/100 kcal (0.54 g/100 kJ) should be scientifically substantiated, clinically evaluated when needed, and assessed by a competent national and/or regional authority who may deviate from this threshold as appropriate.	The approach to evaluate follow-up formula based on hydrolysed protein, containing less than 2.25 g protein/100 kcal, is aligned with the infant formula standard. It is not logical to implement stricter requirements for this older age group (6-12 months). A last sentence is proposed to give competent authority flexibility to deviate from this threshold.
Draft	**Vietnam's proposal**	**Rationale**
3.2.3 DHA the minimum of 20 mg/100kcal and the GUL of 50 mg/100kcal	**3.2.3 DHA** Vietnam supports the GUL of DHA is 50mg/100 kcal. Vietnam proposes to reconsider setting the minimum level of 20mg/100kcal DHA.	**Setting Minimum level of DHA is** inconsistent with Codex IF Standard which IF standard does not set up DHA's minimum level. At present time there is insufficient scientific data for setting minimum level of DHA in this product.
Draft	**Vietnam's proposal**	**Rationale**
3.1.3 c) footnote 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	[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) of available carbohydrate. 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].	Vietnam supports the exclusion of all references to 'sweet taste' from footnote 4 because it is complex, subjective and it is not enforceable.

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.]		
Draft	**Vietnam's proposal**	**Rationale**
3.1.3 d) vitamin D3 **Maximum** [4.5] µg/100kcal	**Text at STEP 3** Vietnam supports the Maximum level of 4.5 µg/100kcal.	This text is still in square brackets. Vietnam supports the maximum limit at 4.5 µg/100kcal. There is no safety concerns regarding to that maximum level.
Draft	**Vietnam's proposal**	**Rationale**
3.2.1 In addition to the essential compositional requirements listed under 3.1.3 Section B, other ingredients, substances or nutrients may be added to [name of the product] for young children where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated by national and/or regional authorities and demonstrated by generally accepted scientific evidence. Optional ingredients listed in 3.2.3 Section A are also permitted.	**3.2.1** In addition to the compositional requirements listed under 3.1.3 Section B, other ingredients, may be added to [name of the product] for young children **in order to provide substances for particular nutritional purposes**. The safety and suitability of the optional ingredient**s** at the level of use, **shall be** evaluated and demonstrated by generally accepted scientific evidence. Optional ingredients listed in 3.2.3 Section A are also permitted **subject to 3.2.2 Section B[1].**	- Alignment with the Codex Infant Formula Standard with regard to how the words 'ingredient' and 'substance' are used. - Deletion of the requirement for evaluation by a national or regional authority as this is more stringent than is applied to optional ingredients in the Infant Formula standard and to optional ingredients in Section A of this standard.