CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 5 **CX/NFSDU 16/38/6-Add.2**

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

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Hamburg, Germany

5 – 9 December 2016

REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987)

Comments of Ecuador, the European Union, Malaysia, Thailand, Vietnam and IFT

ECUADOR

(i) Comentarios generales

Ecuador apoya el documento en revisión a la Norma para preparados complementarios, principalmente resalta la importancia que el documento se preparó en dos secciones, la sección A qué se refiere a los preparados complementarios para lactantes de más edad y la sección B trata de preparados complementarios para niños pequeños. Sin embargo Ecuador emite determinadas recomendaciones a continuación detalladas.

(ii) Comentarios específicos

Si bien Ecuador está de acuerdo con la sección 2.1.1 Definición del Producto, se solicita considerar la inclusión de la siguiente frase al final del párrafo, con el fin de ratificar la importancia de la lactancia materna en este grupo de lactantes de más edad:

[Por preparados complementarios para lactantes de más edad se entiende todo producto destinado a ser utilizado como la parte líquida del régimen alimentario de los lactantes de más edad cuando se introduce la alimentación complementaria.] **siendo prioritario la alimentación con leche materna hasta los 24 meses de edad.**

En la sección 2.2 Definición del Producto, se solicita considerar lo siguiente:

Los preparados complementarios [para lactantes de más edad y (nombre del producto) para niños pequeños] se elaboran por medios físicos exclusivamente y se envasan para evitar **su descomposición** ~~**putrefacción**~~ y contaminación en todas las condiciones normales de manipulación, conservación, ~~**y**~~ distribución **y comercialización** en el país en que se vende el producto.

Justificación: Ecuador sugiere incluir el término “comercialización” ya que al vender, exhibir u ofrecer al mercado un producto, puede existir algún tipo de contaminación ya sea por el medio que lo rodea, el ambiente, entre otros factores.

En la Sección A, Preparados complementarios para lactantes de más edad, se sugiere lo siguiente: En el punto 3.1.1 y 3.3.2 incluir los término “ de calidad” y “seguros”, quedando los párrafo de la siguiente manera:

Los preparados complementarios [para lactantes de más edad] son productos a base de leche de vaca o de otros animales o mezclas de estas y/u otros ingredientes que se ha demostrado que son de **calidad**, inocuos, **seguros** e idóneos para la alimentación de los lactantes de más edad.

Además de los requisitos de composición indicados en las secciones 3.2.4 a 3.2.6, se podrán añadir otros ingredientes o sustancias a los preparados complementarios para lactantes de más edad cuando la **calidad**, inocuidad, **seguridad** y la idoneidad del ingrediente facultativo con fines nutricionales concretos, en su nivel de uso, hayan sido evaluadas y demostradas mediante una evidencia científica generalmente reconocida.

Justificación: Ecuador sugiere incorporar los términos señalados con la finalidad de que se garantice que los ingredientes a utilizarse estén libres de cualquier contaminación ya sea por agentes microbiológicos, químicos o agentes físicos externos.

En la Sección B, Preparados complementarios para niños pequeños, se sugiere lo siguiente:

De igual manera Ecuador sugiere incluir en esta sección en los párrafos de las secciones 3.1.1 y 3.2 los términos “de calidad” y “seguros “según corresponda, bajo los mismos criterios expuestos en la sección A.

En la sección 3.2 ingredientes facultativos Ecuador apoya los siguientes conceptos de las dos alternativas expuestas:

[Además de los requisitos de composición esencial indicados en el punto 3.1.3 de la sección B, se podrán añadir otros [nutrientes,] ingredientes o sustancias a [nombre del producto] para niños pequeños cuando la inocuidad y la idoneidad del [nutriente, el] ingrediente [o la sustancia] facultativo[s] con fines nutricionales concretos, en su nivel de uso, hayan sido evaluadas y demostradas mediante una evidencia científica generalmente reconocida.]

3.2.3 [Cuando se añada cualquiera de estos [nutrientes,] ingredientes o sustancias, el [nombre del producto] para niños pequeños deberá contener cantidades suficientes para lograr el efecto deseado.]

EUROPEAN UNION

The European Union (EU) would like to thank New Zealand, France and Indonesia for their work on document CX/NFSDU 16/38/6. The EU would like to offer the following preliminary general comments as regards Follow-Up Formula for young children.

On 31 March 2016, the European Commission adopted a report on young-child formulae[1] (in CODEX language, "Follow-Up Formula for young children"). In the report, the Commission provided a detailed picture of the market of young-child formulae in the EU and identified a number of issues related to these products. It concluded that, on the basis of the information available, there is no need to lay down specific requirements in the EU legal framework for these products: the correct and complete application of the general framework of EU food law seems sufficient to adequately regulate them.

The report's conclusions are based on the EU situation (both with respect to the market for these products and the legal framework applicable to them) and the EU continues to see the merits of regulating these products in the Codex Standard on Follow-Up Formula, taking into account the differences between the situation in the EU and globally. For this reason, the EU continues to support the relevant work being carried out in CCNFSDU.

As noted in previous meetings of CCNFSDU as well as in previous consultations of the eWG, the EU sees with favour the structured approach proposed by the eWG Chairs (mandatory (core) composition + flexibility for national/regional authorities to establish additional mandatory requirements + possibility for operators to add additional nutrients/substances voluntarily under certain conditions). The EU also supports the three principles developed by the Chairs of the eWG to guide the setting of mandatory compositional requirements for Follow-Up Formula for young children (i.e. contribution to the nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale; contribution of adequate amounts of key nutrients from cows' milk; nutritional quality and integrity of the product). However, the EU believes that the application of these principles should closely take account of the role of Follow-Up Formula in the diet of young children. As the European Food Safety Authority noted in 2013[2], these products are one of the means to increase intakes of certain nutrients at risk of inadequacy for some young children, but have no unique role and cannot be considered as a necessity to satisfy the nutritional requirements of young children when compared to other foods that may be included in their normal diet. In this context, it must be kept in mind that young children have an increasingly diversified diet, so that the relative contribution of Follow-Up Formula to their energy and nutrient requirements decreases with time.

In light of the above, the EU is of the view that CCNFSDU should exert particular care to make sure that the revised Standard does not become excessively prescriptive and detailed as regards compositional requirements for Follow-Up Formula for young children. The EU would find it difficult to support a Standard that is excessively prescriptive for Follow-Up Formula for young children, given that this would be unjustified from a scientific point of view, and would on the contrary give excessive recognition to the role of the products in the diet of young children. In this context, the EU would like to recall that CCNFSDU37 agreed that the principle of "less prescription" should be a key principle to guide the establishment of the Standard provisions for Follow-Up Formula for young children. This principle is all the more valid given that, in any case, the eWG Chairs propose to leave flexibility to national/regional authorities to require the mandatory fortification of Follow-Up Formula for young children with additional nutrients to meet the specific nutritional needs of young children in their territory.

The EU is confident that CCNFSDU will take a cooperative approach on the matter in order to fruitfully advance during the December meeting.

[1] Report from the Commission to the European Parliament and the Council on young child formulae (COM (2016) 169 final), http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0169&from=EN

[2] European Food Safety Authority, 2013. Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. EFSA Journal 2013;11(10):3408,

MALAYSIA

General Comments:

Malaysia supports development of 2 separate product categories, with a point differentiation at 12 months i.e. one category for older infants from 6-12 months and a second category for young children from 12-36 months.

In other words, Malaysia would like to propose the revision of the Standard to consider establishing two separate product categories:

i) Follow-up Formula

ii) Formulated Milk Powder for Children or other similar terminology

This has been the position taken by Malaysia since the commencement of discussions on this agenda item.

ESSENTIAL COMPOSITION OF FOLLOW-UP FORMULA FOR OLDER INFANTS (6-12 MONTHS)

Recommendation 1

Malaysia agrees to set the minimum protein content at 1.8 g/100 kcal in line with Codex Infant Formula Standard. Malaysia recommendation is based on the principle that protein in follow-up formula for older infants (6 - 12 months) should follow the recommendation of Codex Infant Formula Standard to ensure that product provides adequate nutrition.

Footnote 2

Malaysia supports the value of 6.25 as a conversion of nitrogen to protein in other soy products. Malaysia would like to refer to the Codex Standard for Soy Protein Products (CODEX STANDARD 175-1989) which uses a nitrogen to protein conversion factor of 6.25.

Furthermore, the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985) also uses the factor of 6.25 for conversion from nitrogen to protein.

Therefore, Malaysia is of the opinion that there should be consistent usage of nitrogen conversion factor in different Codex documents, and that the appropriate conversion factors for soy bean based Infant Formula and follow-up formula and other soy products should follow the CODEX STANDARD 175-1989, ie 6.25.

Footnote 6

Malaysia supports the footnote 6 and would like to retain a statement which state that formulas containing lower protein than minimum would require clinical evaluation. Therefore, Malaysia proposes the following text:

[[6)]Follow-up formula based on non-hydrolysed /intact milk protein containing [~~less than 2~~ 1.65 to 1.8 g protein/100 kcal] and follow-up [formula based on hydrolysed protein [containing less than 2.25 g protein/100 kcal] should be clinically evaluated **by a competent national and/or regional authority**.

Recommendation 2

Malaysia agrees to set the minimum vitamin K content at 4µg/100 kcal which is based on the principle that vitamin K in follow-up formula for older infants (6 - 12 months) should follow the recommendation of Codex Infant Formula Standard.

Recommendation 3

Malaysia agrees to set the minimum vitamin C content at 10mg/100 kcal which is based on the principle that vitamin C in follow-up formula for older infants (6 - 12 months) should follow the recommendation of Codex Infant Formula Standard.

Recommendation 4

Malaysia agrees to set the GUL zinc content at 1.5 mg/100 kcal which is based on the principle that zinc in follow-up formula for older infants (6 - 12 months) should follow the recommendation of Codex Infant Formula Standard.

Recommendation 5

Malaysia is of the opinion that minimum amount is required to ensure a significant amount is present to provide the intended benefit effect and this is in line with Malaysia's regulation that requires a minimum level to be present to make content claim.

Recommendation 6

Malaysia agrees with the paragraphs 3.3.2.4 and 3.3.2.5 and propose to remove the square brackets. Malaysia

also would like to propose to allow other specific bacterial strains that have been proven safe and suitable for use by generally accepted scientific evidence for particular nutritional purposes. Therefore, the additional wordings are as follows:

3.3.2.4 [Only L(+) lactic producing cultures may be used for the purpose of producing acidified follow-up formula for older infants.]

3.3.2.5 [The safety and suitability of the addition of specific strains of L(+) lactic acid producing cultures **and other specific bacterial strains** for particularly nutritional purposes, at the level of use, shall be demonstrated by generally accepted scientific evidence. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable bacteria to achieve the intended effect.]

FRAMEWORK FOR THE ESSENTIAL COMPOSITION OF FOLLOW-UP FORMULA FOR YOUNG CHILDREN (12-36 MONTHS)

Recommendation 7

For the purpose of this discussion, Malaysia agrees to divide the Standard for Follow-up Formula in two separate parts as follows:

i) Follow-up Formula for older infants (6 – 12 months)

ii) Product for young children (12 - 36 months)

Recommendation 8

For the proposed framework for the composition of follow-up formula for young children for optional ingredient, Malaysia agrees with the option 2.

Recommendation 9

Malaysia supports establishing a minimum energy density of 45 kcal/100mL as follows:

3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the product shall contain per 100 mL not less than **[45 kcal (188 kJ)]** and not more than 70 kcal (293 kJ) of energy.

Recommendation 10

In establishing the amount of carbohydrate, protein and fat for follow-up formula for young children aged 12-36 months, Malaysia proposes that the basis for calculation of the levels of these nutrient would be to meet about one-third of the Recommended Nutrient Intake (RNI) of young children. This approach is taken, recognizing the role of the product as an add-on to the other family food that young children will be taking.

Recommendation 11

Malaysia supports setting minimum quality requirement for protein and proposes this to be in line to the standard of follow-up formula for older infants.

Recommendation 12

Malaysia is of the view that it is not necessary to include a mandatory requirement for the addition of α-linolenic acid. The fact that the fat component in follow-up formulas is from cow's milk and that specific recommendations have already been proposed for DHA. Therefore, the recommendation to include a mandatory requirement for the addition of α-linolenic acid is irrelevant.

Recommendation 13

Malaysia agrees that commercially hydrogenated oils and fats should not be used to follow-up formula for young children (12-36 months).

Recommendation 14

Malaysia would like to seek clarification on the different values in the proposed footnote for follow-up formula for young children (12-36 months) which states that sugars, other than lactose, should not exceed 10% of the available carbohydrate and in the proposed footnote 9 (Appendix 5) for follow-up formula for older infants (6-12 months) which states that sugars should not exceed 20% of the available carbohydrate.

Recommendation 15

Malaysia proposes that in setting the minimum requirement for vitamins and minerals for young children (12-36 months), the general approach taken should be based on about one-third of the Recommended Nutrient Intake (RNI) of children of this age group.

Iron

Data shows that iron deficiency is still a public health concern among young children in Malaysia. Therefore, the maximum level or GUL should not be set. Excessive addition may not be a concern as the level of addition is self-limiting in a way.

Vitamin C

Malaysia is of the view that the maximum level of Vitamin C need not be set. Excessive addition may not be a concern as the level of addition is self-limiting in a way.

Recommendation 16

Malaysia proposes that the minimum requirement for Calcium, Riboflavin, Vitamin B12 for young children (12-36 months) should be based on about one-third of the Recommended Nutrient Intake (RNI) of children in this age group.

Riboflavin

Malaysia is of the view that the maximum level of Riboflavin need not be set. Excessive addition may not be a concern as the level of addition is self-limiting in a way.

Vitamin B12

Malaysia is of the view that the maximum level of Vitamin B12 need not be set. Excessive addition may not be a concern as the level of addition is self-limiting in a way.

Recommendation 17

Malaysia proposes that the minimum level for Vitamin A for young children (12-36 months) should be based on about one-third of the Recommended Nutrient Intake (RNI) of children in this age group.

Recommendation 18

Malaysia proposes that the minimum level for Vitamin D for young children (12-36 months) should be based on about one-third of the Recommended Nutrient Intake (RNI) of children in this age group.

Malaysia is of the view that the maximum level of Vitamin D should not be set. Available data shows that the Vitamin D deficiency is still a public health concern in Malaysia. Furthermore, excessive addition may not be a concern as the level of addition is self-limiting in a way.

Recommendation 20

To facilitate discussion, Malaysia has no objection with the proposed Standard for Follow-up Formula to be presented in two separate parts at this time, as the names of the 2 categories have not been finalised

However, if the product for young children aged 12 – 36 months is eventually not called Follow-up Formula, Malaysia would like to propose that there should be two separate standards for these two distinctly different products. This product for young children will eventually have a distinctly different composition and intention for use that it would no longer be appropriate to be called a “follow-up formula”. Malaysia proposes the name of the product as Formulated Milk Powder for Children or words of similar meaning (12 - 36 months).

Recommendation 21

Malaysia is of the opinion that product for young children age 12-36 months is more appropriate to be called as “Formulated Milk Powder for Children” or other similar terminology because the product is formulated to meet the needs of young children (12 to 36 months). For the establishment of minimum levels of various nutrients, we have proposed that this be based on the recommended nutrient intake (RNI) for these young children. The product is therefore formulated to meet the nutritional needs of young children, and a name to reflect this would be appropriate.

The nutrient composition of this product is entirely different from that for older infants. It is also positioned to be used differently as compared to the product for older infants as the dietary pattern and needs are distinctly different. The name must be one that enables consumers to clearly differentiate between the two categories of products. For these various reasons, it would not be appropriate to name this product for young children as “formula-up formula”. The name should also not be too generic such as fortified milk product as many milk products can be fortified.

THAILAND

General comments

We agree with the document in principle.

Specific comments

Our comments for specific sections of the document are as described below.

Section 3: Essential Composition Of Follow-Up Formula For Older Infants (6-12 Months)

Recommendation 1

1) Protein requirements

We agree with protein requirements as proposed:

Protein

Unit	Minimum	Maximum	GUL
g/100 kcal	~~[~~1.8~~]~~	~~[~~3.0~~]~~	-
g/100 kJ	~~[~~0.43~~]~~	~~[~~0.72~~]~~	-

2) Footnote 2)

For the last sentence, a square bracket should be removed from the text "a nitrogen conversion factor of 5.71 in other soy products". However, the word "other" before "soy products" should be deleted, because the requirement concerns the nitrogen conversion factors for different products that include milk, other milk products and soy products.

So, the last sentence should read:

"[2)] For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, ……The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of ~~[~~***5.71***~~]~~ as a specific factor for conversion of nitrogen to protein in ~~***other***~~ soy products."

3) Footnote 5

To be consistent with the first sentence, it is proposed to add the words "and goat" before "milk protein" in the second sentence. So, this footnote should read:

"[5)] The minimum value applies to cows' and goats' milk protein. For follow-up formula based on non- cows' ***and goat***' milk protein other minimum values may need to be applied"

Recommendation 2

Vitamin K requirements

We agree with the revised minimum level for vitamin K as proposed, since it is appropriate and world-widely used:

Vitamin K

Unit	Minimum	Maximum	GUL
g/100 kcal	~~[~~4.0~~]~~	-	27
g/100 kJ	~~[~~1.0~~]~~	-	6.5

Recommendation 3

Vitamin C requirements

We agree with the revised minimum level for vitamin C as proposed:

Vitamin C

Unit	Minimum	Maximum	GUL
g/100 kcal	~~[~~10~~]~~	-	70[16)]
g/100 kJ	~~[~~2.4~~]~~	-	17[16)]

Recommendation 4

1) Zinc requirement

We agree that the minimum guiding upper level for Zinc should be revised as proposed in order be practical in technologies of production:

Zinc

Unit	Minimum	Maximum	GUL
g/100 kcal	0.5	-	~~[~~1.5 ~~]~~
g/100 kJ	0.12	-	~~[~~0.36~~]~~

2) Footnote 20

It is proposed to remove the proposed additional words "and maximum value of 1.25 mg/100 kcal (0.3/100 kJ), meanwhile the word "applies" should be retained.

So, this footnote should read:

" (20For follow-up formula based on soy protein isolate a minimum value of 0.75mg/ 100kcal (0.18mg/ 100 kJ) ***~~[and maximum of 1.25 mg/100 kcal (0.3/100 kJ)~~ applies~~.]~~"***

Recommendation 5

- the optional addition of docosahexanoic acid

Considering FAO's recommended adequate intakes of long chain polyunsaturated fats of between 0.2-0.36% of total fatty acids, it is agreed with the drafting of the optional addition of docosahexanoic acid as proposed:

Docosahexanoic acid

Unit	Minimum	Maximum	GUL
% of fatty acids	-	-	0.5

Recommendation 6

- Optional addition: L(+) lactic acid producing cultures

It is proposed that 3.3.2.4 should be revised; meanwhile 3.3.2.5 should be deleted in order to be aligned with the Infant Formula Standard. And, the addition of L(+) lactic acid producing culture are used for further purposes, other than the technological function and for a nutritive purpose that are specified in this section. So, the section should read as follows:

"~~]~~ 3.3.2.4Only L(+) lactic producing cultures may be used ~~.for the purpose of producing acidified follow-up formula for older infants.]~~

~~] 3.3.2.5The safety and suitability of the addition of specific strains of L(+) lactic acid producing cultures for particularly nutritional purposes, at the level of use, shall be demonstrated by generally accepted scientific evidence. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable bacteria to achieve the intended effect.]~~ "

Section 4 Framework for the Essential Composition of Follow-Up Formula for Young Children (12-36 Months)

Recommendation 7

- Appendix 5

It is agreed to divide the Standard for Follow-up Formula in to two separate parts as presented in Appendix 5. The standard will include Section A that will apply to the essential composition and labelling of follow-up formula for older infants, and Section B that will deal with the essential composition and labelling of product for young children.

Recommendation 8

- Mandatory (core) composition

1) We agree with the proposed revision of the mandatory (core) composition of follow-up formula for young children.

2) For a table on Page 24, the sequence of nutrients in the table should be consistent with a nutrient list of other CCNFSDU's documents.

- Optional Additions

We agree with option 2 for optional addition as proposed by the EWG.

Section 5 Requirements for the Essential Composition of Follow-Up Formula For Young Children (12-36 Months)

Recommendation 9

- Energy density

1) We agree with the establishment of requirements for energy density.

2) However, the "additional option for further discussion" concerning products for young children of more than 24 months of age should be removed from the requirement to avoid confusion. So the section should read:

"3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than [60 kcal (250 kJ)] and not more than 70 kcal (293 kJ) of energy.

~~*Additional option for further discussion:*~~

~~*[For products formulated for young children of more than 24 months of age, the product when prepared ready for consumption shall contain per 100 mL not less than 45 kcal (kJ)]"*~~

3) For young children of more than 24 months of age, CCNFSDU may consider further wording added to the requirements to specify that national and/or regional competent authorities should develop low energy or fat products for this group of children.

Recommendation 10

- Available carbohydrates

We agree to include a maximum limit for total carbohydrates; however the unit of the level of available carbohydrates should be changed from "mg" to "g". So, the section should read:

"Available carbohydrates

*The level of available carbohydrates should not exceed ~~[~~12 g per 100 kcal (2.9 **g** ~~**mg**~~ per 100 kJ) ~~]~~*

***Additional options for further discussion**:*

The level of protein shall not be less than 1.8 g/100 kcal

The level of total fats shall not be less than 4.0 g/100 kcal"

Recommendation 11

- minimum protein quality requirements

It is agreed to include minimum protein quality requirements specifying that "The quality of protein shall not be less than 85% of that of casein" to be useful information for a producer and consumer.

Recommendation 12

- the addition of α- linolenic acid requirement

The addition of α-linolenic acid (in the form of glycerides) of not less than 50 mg per 100 kcal (12 mg per 100 kJ) should be included as a mandatory requirement.

Recommendation 13

- commercially hydrogenated fats and oils

It is agreed that commercially hydrogenated fats and oils should not be used in products for young children.

Recommendation 14

- types of carbohydrates suitable for [name of product] for young children

1) We agree with the proposed text on types of carbohydrates suitable for [name of product] for young children as follows:

"Lactose should be the preferred carbohydrates in [name of product] based on milk protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source. Sugars, other than lactose, should not exceed 10% of available carbohydrate".

2) Clear descriptions should be provided for the words "Sugars, other than lactose" in the last sentence

3) Further descriptions for a carbohydrate source of products based on soy protein isolate should be provided.

Recommendation 15

- iron and vitamin C levels

We agree with the proposed iron and vitamin C levels in products for young children as follows:

Iron	Minimum	Maximum	GUL
Unit			
mg/100 kcal	~~[~~1.0 ~~]~~	~~[~~3.0~~]~~	-

~~[~~ For [name of product] based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36 mg/100 kJ) applies.~~]~~

Vitamin C	Minimum	Maximum	GUL
mg/100 kcal	~~[~~ 10~~]~~	-	~~[~~ 70 ~~]~~
mg/100 kJ	~~[~~ 1~~]~~	-	~~[~~ 17 ~~]~~

Recommendation 16

- calcium, riboflavin and vitamin B12 levels in [name of product] for young children

We agree with calcium, riboflavin and vitamin B12 levels for young children as proposed, however "Additional further consideration" should be deleted from the requirement. So, the section should read as follows:

Calcium

Unit	Minimum	Maximum	GUL
mg/100 kcal	~~[~~ 90 ~~]~~	-	~~[~~ 280 ~~]~~

Riboflavin

Unit	Minimum	Maximum	GUL
mg/100 kcal	~~[~~ 80 ~~]~~	-	~~[~~ 500 ~~]~~

Vitamin B12

Unit	Minimum	Maximum	GUL
mg/100 kcal	~~[~~ 0.1 ~~]~~	-	~~[~~ 2.0 ~~]~~

~~**Additional Option for further consideration:**~~

~~[~~Ratio calcium/phosphorous~~]~~

~~Min~~	~~Max~~
~~[1:1]~~	~~[2:1]~~

Recommendation 16

- Zinc

Zinc should be included as a mandatory (core) nutrient for addition to products for young children with the proposed level as follows:

Zinc

Unit	Minimum	Maximum	GUL
mg/100 kcal	~~[~~ 0.5 ~~]~~	-	~~[~~1.8 ~~]~~

[20] For Follow-up formula based on soy protein isolates a minimum value of 0.75 mg/100 kcal (0.18 mg/100 kJ) [and maximum of 1.25 mg/100 kcal (0.3/100 kJ) applies.].

Recommendation 17

- Vitamin A

Vitamin A should be included as a mandatory (core) nutrient for addition to [name of product] for young children with the proposed level as follows:

Vitamin A

Unit	Minimum	Maximum	GUL

µg RE10) /100 kcal	~~[~~ 60 ~~]~~	~~[~~ 180 ~~]~~	-
µg RE10) /100 kJ	~~[~~ 14 ~~]~~	~~[~~ 43 ~~]~~	-

[10)] expressed as retinol equivalents (RE)

1 µg RE = 3.33 IU Vitamin A = 1 µg all-trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

Recommendation 18

- Vitamin D

Vitamin D should be included as a mandatory (core) nutrient for addition to [name of product] for young children with the proposed level as follows:

Vitamin D

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

Recommendation 19

- Sodium level

We agree with the recommendation for sodium level of maximum 85 mg/kg for products for young children as proposed:

Sodium

Unit	Minimum	Maximum	GUL
µg /100 kcal	-	~~[~~ 85 ~~]~~	-
µg /100 kJ	-	~~[~~20 ~~]~~	-

Recommendation 20

We agree to divide the Standard for Follow-up Formula in to two separate parts as presented in Appendix 5. Section A will refer to the essential composition and labelling of follow-up formula for older infants, and Section B will deal with the essential composition and labelling of product for young children. Appendix 5

Recommendation 21

- product definition (section 2.1.2)

To be consistent with the standards for follow up formula and infant formula, the term "young child formula" should be used in the product definition instead of proposed terms including fortified milk product, processed milk product for young children and follow-up formula for young children. So, the section should be read:

"[Follow-up formula for older infants means a product intended for use as the liquid part of the diet for older infants when complementary feeding is introduced, and ***young child formula*** ~~***[Fortified milk product] OR [Processed milk product for young children] OR [Follow-up formula for young children]***~~ *[means a product intended for use as a liquid part of the progressively diversified diet when nutrient intakes may not be adequate to meet the nutritional requirements of young children.]".*

VIETNAM

GENERAL COMMENTS

Vietnam supports the proposed draft revision to the Standard for Follow up Formula which presented in CCNFSDU 38 agenda final paper with such comments as following:

A. SECTION 3: FOLLOW-UP FORMULA FOR OLDER INFANTS (6-12 MONTHS):

Regarding to Section 3.2.1. Protein minimum:

Vietnam supports a minimum protein level of 1.65 g/100 kcal, provided that any product which has the level within this range of 1.65-1.8g/100 kcal should be clinically evaluated by a national/regional authority.

B. SECTION 5: FOLLOW-UP FORMULA FOR YOUNG CHILDREN (12-36 MONTHS):

Vietnam supports the first option about extensive prescribed mandatory (core) composition of follow-up formula for young children which was presented in the table of Section 5.1. In addition, Vietnam proposes to add two more micronutrients into the table mentioned above: Iodine and folic acid due to their important role in children's development.

The proposed levels of these nutrients in the table were presented at the table below:

No.	Extensive prescribed mandatory (core) composition	Min/Max level	Rationale
5.2	Energy	45-70 kcal/100ml; without a differentiation at 24 months	There are RNIs for children at the age of 1-3 years. There are no scientific evidences for benefit of differentiation at the age of 24 months.
5.3.1	Carbohydrates	maximum carbohydrate level of 14g/100 kcal	As aligned with revised requirements for follow-up formula of older infants
5.3.1	Total Fat	3.5-6g/100kcal	To ensure an appropriate macronutrient profile
5.3.1	Protein	1.5-5.5g/100kcal	To ensure an appropriate macronutrient profile. The malnutrition is particular problem not only in South East Asia region but also in Vietnam. Protein is a key macronutrient for children development, therefore protein should be one of the mandatory (core) nutrients which are crucial to ensure that follow-up formula contains a nutritionally appropriate and balance range of macronutrients.
5.5.1	Essential Fatty acids	Support an approach that mandates the addition of linoleic acid, 300 mg – 1400 mg (GUL)/100 kcal.	Linoleic acid is an essential fatty acid, and an appropriate ratio between linoleic acid and alpha-linolenic acid is recommended. This proposed level is aligned with the Infant Formula Standard and the current Follow-up Formula Standard.
5.7	Vitamin C	4.5 – 70 mg/100 Kcal	As proposed by international expert group
5.9	Zinc	0.5-1.8 (GUL) mg/100 kcal	Due to the high rate of Zinc deficiency in Vietnam and some other region in the world, it's the same GUL specified in the Infant Formula Standard, and the Follow-up formula is only a part of the weaning diet of the children.
5.10	Vitamin A	60-225 µg RE/100 kcal.	Due to the high rate of Vitamin A deficiency in Vietnam and some other regions in the world, and the history of apparent safe use of the current level.
5.11	Vitamin D	1.5 - 4.5 µg /100 kcal	Due to the high rate of Vitamin D deficiency in Vietnam and some other regions in the world, and vitamin D's importance in the diet.
	Iodine	Need to be developed. Could consider the level in the current Follow-up Formula Standard: Min 5.0 mcg/100 kcal	Due to their importance role in children's development.
	Acid Folic	Need to be developed. Could consider the level in the current Follow-up Formula Standard: Min 4 mcg/100 kcal.	Due to their importance role in children's development.

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Recommendation 1:

We support the revised protein requirement and removal of the square brackets from the conversion factor.

Recommendation 2:

We support the vitamin K minimum level at 4 mg/100kcal due to insufficient evidence to deviate from this value.

Recommendation 3:

We agree with the Chairperson's recommendation to maintain the minimum vitamin C level at 10 mg/kcal as a compromise.

Recommendation 5:

We do not agree with the Chair's recommendation to leave the amount of the optional ingredient DHA to the discretion of national/regional authorities and believe that the text should reflect that "when DHA is added it should provide a minimum of 0.3% of fatty acids, and that ARA must be added at the same or higher level as DHA, and that amounts of EPA must not exceed those of DHA."

In the most recent CCFSNDU agenda paper, the Chairs acknowledge mixed views within the working group regarding the need for a minimum requirement for the optional addition of DHA. Based on these mixed views, the Chairs recommend acceptance of text drafted at CCNFSDU37 which established only a GUL and allows national and/or regional authorities to deviate from this suggested condition, and the condition that ARA be added at the same or higher level as DHA, and EPA must not exceed DHA. However, this option does not establish a minimum level of addition when DHA is to be added.

We believe this approach fails to provide scientifically-based guidance to countries that lack the resources to determine a country-specific value for addition. The value of 0.3% of total fatty acids for voluntary addition of DHA is consistent with the reported world-wide average for DHA in human milk which is 0.32%±0.22 (range 0.06 to1.4%) and for ARA is 0.47%±0.13 (range 0.24 to 1.0%) (1) and meets the recommendations of FAO and EFSA (2, 3). By setting a minimum level of 0.3% DHA in FUF when it is added would ensure that formula fed infants consume physiologically meaningful levels to promote proper development and long-term health. Evidence was provided to the Committee by IFT in 2015, and is now available as a peer-reviewed publication (4), documenting the global deficit of DHA and ARA intakes in non-breast fed infants and children through the use of publically held transparent nutrient intake database information from recognized authoritative scientific bodies (RASBs). Other publications show that consuming DHA in the amounts provided by breastmilk is safe and not excessive (5). The level of 0.3% fatty acids as DHA and specifications for ARA and DHA set evidence-based benchmarks from which higher national/regional standards for FUF can be established, as needed, based on local dietary patterns and cultural practices. The approach of specifying a minimum amount of addition when the addition is made is consistent with the principle noted in 3.3.2.2. of the proposed revision of the FUF standard, "when any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect, considering levels in human milk."

The Chairs propose their text in part by noting that "…minimum values for optional ingredients have not been established for any other optional ingredients listed in either the Codex Infant Formula Standard, or the proposed draft Standard for Follow-up Formula (REP16/NFSDU Appendix III)." While this statement accurately describes these two standards, the establishment of minimum values for optional ingredients within other Codex documents relevant to this age group has clear precedent. For example, the Codex Guidance on Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991) provides for optional addition of vitamins and minerals and notes the following: "6.6.1.3 If the dietary intake data for the target population is not available, the vitamins and minerals listed in the Table in the Annex to these Guidelines can be used as a reference for the selection of particular vitamins and minerals and their amounts for addition to a Formulated Complementary Food."

References for Recommendation 5

1. Brenna TJ. 2016. Nutr Rev 74:329-336.
2. Food and Agricultural Organization of the United Nations (FAO), 2010. FAO Food and Nutrition Paper 91.
3. EFSA, 2009. EFSA Journal 941:1-14.
4. Forsyth et al., 2016, Ann Nutr Metab 69(1):64-74.
5. Lien, 2009, Prostaglandins Leukot Essent Fatty Acids. 81(2-3):125-32.

Regarding Recommendation 8

The Chairs propose two options for the addition of optional ingredients for follow-up formula for young children. Option 1 uses the essential composition of follow-up formula for older infants and option 2 foresees a principles-based approach.

Option 1, which uses the essential composition of formula for older infants as a reference point, provides much more defined guidance for the development of nutritionally-adequate formula for young children. However, limiting to only the essential ingredients ignores the extensive deliberations and evaluations associated with decisions to allow certain optional ingredients, at specified levels, in formula for older infants. It is respectfully requested, therefore, that both the essential and optional ingredients decided upon for older infants be recognized for formula for young children. This is particularly relevant for DHA where a global deficit has been identified (1) and the dietary precursor to DHA, ALA, has been recognized as limited in the diets of young children world-wide and conversion from ALA to DHA insufficient to meet DHA needs (2, 3).

We prefer option 2 as it opens the possibility to add nutrients, substances, or ingredients which are safe and suitable.

Regarding Recommendation 12

The Chairs recommend a minimum level of ALA for addition in formula intended for young children. This is an important recommendation, but does not go far enough. The Chairs note in their discussion that, "Dietary intake data from low income countries have indicated that mean intakes of α-linolenic acid and DHA were low…" Given that a deficit of DHA is already recognized in low income countries, and it is known that conversion of ALA to DHA is poor (2, 3), why then would the composition of formula for young children not benefit from allowance for optional addition of DHA, as described for older infants? In fact, two recent evidence-based reviews (Brenna, 2016; Carlson and Colombo, 2015) and results from one new study (Hatanaka et al., 2016) confirm the inadequacy of ALA to meet needs of DHA in early life. Therefore, we respectively request that optional addition of DHA, as described in recommendations for older infants, be included here.

References for Recommendations 8 and 12

1. Forsyth et al., 2016, Ann Nutr Metab. 69(1):64-74.
2. Pawlosky RJ, Lin YH, Llanos A, et al. 2006, Pediatr Res. 60: 327–333.
3. Carnielli VP, Simonato M, Verlato G, et al. 2007, Am J Clin Nutr. 86:1323-30.
4. Brenna TJ. 2016, Nutr Rev. 74:329-336.
5. Carlson, S.E. and Colombo, J. 2016, Advances in Pediatrics. 63:458-471.
6. Hatanaka et al., 2016, Prostaglandins, Leukot Essent Fatty Acids. 108(2016)51–57.

Recommendation 15:

We agree with the minimum and GUL level for vitamin C and minimum and maximum level for iron.

Recommendation 16:

We agree with the minimum and GUL levels proposed for riboflavin and vitamin B12. For calcium, we believe the minimum level should be increased due to increased requirements.

Recommendation 17:

Vitamin A is a key nutrient in many countries where the risk of deficiency is high and the consequences from its deficiency is major public health issue. We understand the EFSA position regarding the risk of excessive vitamin A intake but believe vitamin A should be on the list of mandatory nutrients with a maximum limit in order to avoid the risk of excessive intake. Therefore we favor the alternative proposal which is in line with the recommendation from Suthutvoravut et al. (2015) (1).

References for Recommendations 17

1. Suthutvoravut et al. 2015, Ann Nutr Metab. 67:119-132.

Recommendation 18:

Vitamin D is a key vitamin with multiple roles including in building bones and immunity. Vitamin D is found in animal derived products which are not necessarily consumed in high quantity by this age group. On a global scale, vitamin D status is insufficient in this population including in sunny countries. In addition, it's not generally accepted that the requirements are higher than previously assumed. This means that the gap in intakes has become even bigger. Therefore, we believe vitamin D is fitting the criteria to be included as mandatory nutrients. We understand the fear of adverse effects so we agree with setting a maximum level instead of a GUL.