CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 5 **CRD 5**
Original language only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-seventh Session
Bad Soden a.T. – Germany
23 – 27 November 2015

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

Comments of Colombia, Ecuador, European Union, India, Kenya, Malaysia, Mexico, Vietnam and IBFAN

COLOMBIA

A continuación, se indica la posición del país frente al documento de fórmulas de continuación, según la solicitud del comité de remitir las observaciones a las recomendaciones por escrito, de conformidad con el Procedimiento uniforme para la elaboración de normas del Codex y textos afines.

1. Colombia, en el punto 5 de "**DESCRIPTION OF FOLLOW-UP FORMULA (SECTION 2)"** apoya la definición y otras definiciones :

2.1 Product Definition
2.1.1 Follow-up formula means a food intended for use as
[a) the liquid part of the diet for older infants when complementary feeding is introduced; and
b) a liquid part of the progressively diversified diet of young children.

2.2 Other Definitions The term **infant** means a person of not more than 12 months of age.
[**Older infants** means persons from the age of 6 months and not more than 12 months of age.]
The term **young child** means persons from the age of more than 12 months up to the age of three years (36 months).

Y recomienda que el punto 2.1.2 sea modificado, así:
[Follow-up formula Follow-up formula is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution.]

2. Colombia, en "**Section 3 - Essential Composition**", esta de acuerdo con la siguiente definición y el componente adicional:

Follow-up formula is a [food], [based on] milk of cows or other animals or a mixture thereof [,] and/or other ingredients which have been [proved]] to be [safe and] suitable [and *nutritionally adequate] [to support growth and development] for [the intended age range].*

[Consumption of the formula should appropriately contribute to normal growth and development of the intended age range].

Recomendación	Posición Colombia
Recommendation 1 That CCNFSDU agree to revise the essential composition for follow-up formula for older infants to align with the requirements specified in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981) for the following nutrients: - Energy - Vitamins: vitamin E, vitamin K, thiamin, riboflavin, niacin,	Colombia apoya que la composición esencial para las fórmulas de continuación este alineada con el estándar de formulas infantiles (CODEX STAN 72-1981) en los nutrientes propuestos.

<table>
<tr><th>Recomendación</th><th>Posición Colombia</th></tr>
<tr><td>vitamin B12, pantothenic acid, vitamin C and biotina.

- Minerals: magnesium, sodium, chloride, potassium

-</td><td></td></tr>
<tr><td>Recommendation 2
That CCNFSDU consider amending the conversion factors in line with the International Standard Unit conversion factors and conventional rounding.</td><td>Colombia apoya la modificación de los factores de conversión de acuerdo con los factores de conversión Internacional y redondeo convencional.</td></tr>
<tr><td>Recommendation 3
That CCNFSDU agree to revise the protein minimum and maximum level and associated footnotes, as follows:
<table><tr><th>Unit</th><th>Minimum</th><th>Maximum</th><th>GUL</th></tr><tr><td>g /100 kcal</td><td>[1.8]5)</td><td>[3.5]</td><td>-</td></tr><tr><td>g /100 kJ</td><td>[0.43]5)</td><td>[0.84]</td><td>-</td></tr></table>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, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 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) For an equal energy value the formula must contain an available quantity of each essential and semi- essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)); nevertheless for calculation purposes the sum of tyrosine and phenylalanine and the sum of methionine and cysteine may be used.

4) Isolated amino acids may be added to ~~Infant F~~ follow-up formula only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used.
5)
The minimum value applies to cow`s <b>[and goats]</b> milk proteína. For follow-up formula base on non- cow`s milk proteína other minimum values may need to be applied. For follow-up formula based on soy proteína isolate, a minimum value of 2.25 g/100 kcal (0.54 g/100 KJ) applies).
~~6) [Follow-up formula based on non-hydrolysed milk protein containing less than [2 g protein/100 kcal] and] infant [formula based on hydrolysed protein containing less than [2.25 g protein/100 kcal] should be clinically evaluated].~~</td><td>Colombia no está de acuerdo con el mínimo de 1.8 g/100 kcal de proteína propuesto.

Propone el valor mínimo de 1.65 g/ 100 kcal, propuesto por los estudios de Koletzko y colaboradores.

Colombia está de acuerdo con las notas al pie 2, 3 y 4.
Considera que en la nota 5, puede cambiarse el termino [y cabras] por Otros animales.

Colombia no esta de acuerdo con la eliminación de la nota al pie 6.</td></tr>
<tr><td>Recommendation 4
That CCNFSDU agree to revise the total fat minimum and maximum level and associated footnotes, as follows:</td><td>Colombia está de acuerdo con los valores máximos y mínimos planteados para grasa total y las notas al pie.</td></tr>
</table>

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<tr><th>Recomendación</th><th>Posición Colombia</th></tr>
<tr><td>

Total Fat [7), 8)]

Unit	Minimum	Maximum	GUL
g /100 kcal	[4.4]	[6.0]	-
g /100 kJ	[1.1]	[1.4]	-

7) Commercially hydrogenated oils and fats shall not be used in follow-up formula
8) Lauric acid and myristic acids are constituents of fats, but combined shall not exceed 20% of total fatty acids. The content of trans fatty acids shall not exceed 3% of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in follow-up formulae. The erucic acid content shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).

</td><td></td></tr>
<tr><td>

Recommendation 5
That CCNFSDU agree to revise the linoleic and alpha-linolenic minimum and maximum level, as follows:
Linoleic acid

Unit	Minimum	Maximum	GUL
mg /100 kcal	[300]	[1400]	-
mg /100 kJ	[72]	[335]	-

α-Linolenic acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	[50]	N.S.*	-
mg /100 kJ	[12]	N.S.	-

*N.S. = not specified

Ratio linoleic acid/ α-Linolenic acid

Min	Max
5:1	15:1

</td><td>Colombia apoya los valores de mínimos planteados para el ácido linoleico, sin embargo recomienda ajustar los valores de Máximos [1400] y [335] a GUL.
Colombia está de acuerdo con la relación propuesta para el ácido linoleico y el α - linolénico</td></tr>
<tr><td>

Recommendation 6
That CCNFSDU agree to consider the addition of DHA, ARA and EPA as optional additions to follow-up formula.

</td><td>Colombia está de acuerdo en considerar que la adición de DHA, ARA y EPA sean adiciones opcionales en las fórmulas de continuación.</td></tr>
<tr><td>

Recommendation 7
That CCNFSDU agree to revise the carbohydrate minimum and maximum level, as follows:
Total Carbohydrates 9)

Unit	Minimum	Maximum	GUL
mg /100 kcal	[9.0]	[14.0]	-
mg /100 kJ	[2.2]	[3.3]	-

9) Lactose and glucose polymes should be the preferred carbohydrates in formula base don cows´milk protein and hydrolysed protein. [Only precooked and/or gelatinised starches gluten-free by nature may be added.] [If needed, sucrose, fructose may be added provided the sum of these does not exceed $\leq$ 20% total carbohydrate.]

</td><td>Colombia está de acuerdo con los valores máximos y mínimos planteados para carbohidratos y la nota al pie.</td></tr>
<tr><td></td><td></td></tr>
</table>

<table>
<tr><th>Recomendación</th><th>Posición Colombia</th></tr>
<tr><td>Recommendation 8
That CCNFSDU agree to retain the current minimum vitamin A composition, and to revise the maximum level and footnote in accordance with the Infant Formula standard, as follows:
Vitamin A
<table><tr><th>Unit</th><th>Minimum</th><th>Maximum</th><th>GUL</th></tr><tr><td>µg RE [10]/100 kcal</td><td>[75]</td><td>[180]</td><td>-</td></tr><tr><td>µg RE [10]/100 kJ</td><td>[18]</td><td>[43]</td><td>-</td></tr></table>10) expressed as retinol equivalents (RE)
1 µg RE = 3.33 IU Vitamin A = 1 µg 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.</td><td>Colombia está de acuerdo con los valores máximos y mínimos planteados para vitamina A y los factores de conversión.</td></tr>
<tr><td>Recommendation 9
That CCNFSDU agree to revise the minimum and maximum for vitamin D as follows:
Vitamin D
<table><tr><th>Unit</th><th>Minimum</th><th>Maximum</th><th>GUL</th></tr><tr><td>µg [11]/100 kcal</td><td>[1.0]</td><td>[3.0]</td><td>-</td></tr><tr><td>µg [11]/100 kJ</td><td>[0.24]</td><td>[0.72]</td><td>-</td></tr></table>[11] Calciferol. 1 µg calciferol = 40 IU vitamin D.</td><td>Colombia está de acuerdo con los valores mínimos planteados para vitamina D y el factor de conversión.

Colombia propone el valor de [4.5] ug/100kcal como máximo</td></tr>
<tr><td>Recommendation 10
That CCNFSDU agree to revise the minimum and GUL for vitamin B6 as follows:
Vitamin B_6
<table><tr><th>Unit</th><th>Minimum</th><th>Maximum</th><th>GUL</th></tr><tr><td>µg /100 kcal</td><td>[35]</td><td>-</td><td>[175]</td></tr><tr><td>µg /100 kJ</td><td>[8.4]</td><td>-</td><td>[41.8]</td></tr></table></td><td>Colombia está de acuerdo con los valores mínimos y de GUL planteados para vitamina B6.</td></tr>
<tr><td>Recommendation 11
That CCNFSDU agree to revise the minimum and GUL for folic acid in accordance with the Infant Formula standard, as follows:
Folic acid
<table><tr><th>Unit</th><th>Minimum</th><th>Maximum</th><th>GUL</th></tr><tr><td>µg /100 kcal</td><td>[10]</td><td>-</td><td>[50]</td></tr><tr><td>µg /100 kJ</td><td>[2.4]</td><td>-</td><td>[12]</td></tr></table></td><td>Colombia está de acuerdo con los valores mínimos y de GUL propuestos para ácido fólico.</td></tr>
<tr><td>Recommendation 12
That CCNFSDU agree to revise the minimum and maximum for iron as follows:
Iron17)
<table><tr><th>Unit</th><th>Minimum</th><th>Maximum</th><th>GUL</th></tr><tr><td>mg /100 kcal</td><td>[1.0]</td><td>[2.0]</td><td>-</td></tr><tr><td>mg /100 kJ</td><td>[0.24]</td><td>[0.48]</td><td>-</td></tr></table>[17) For Follow-up formula based on soy protein isolate a minimum value of 1.5/100 kcal (0.36/100 kJ) and maximum of 2.5 mg/100 kcal (0.6/100 kJ) applies.]</td><td>Colombia está de acuerdo con los valores máximos y mínimos planteados para hierro, así como los valores cuando las fórmulas de continuación están basadas en proteína de soya. Sin embargo sugiere al los expertos y/o al comité establecer un valor GUL para el hierro.</td></tr>
<tr><td>Recommendation 13
That CCNFSDU agree to revise the minimum and GUL for calcium and phosphorous as follows:
Calcium</td><td>Colombia apoya la propuesta de los valores mínimos y de GUL para calcio y el fósforo, así como la relación propuesta para ellos.</td></tr>
</table>

Recomendación	Posición Colombia
Unit / **Minimum** / **Maximum** / **GUL** mg /100 kcal / [50] / - / [180] mg /100 kJ / [12] / - / [43] **Phosphorous** **Unit** / **Minimum** / **Maximum** / **GUL** mg /100 kcal / [25] / - / [100] mg /100 kJ / [6] / - / [24] **Ratio calcium/ phosphorus** **Min** / **Max** 1:1 / 2:1	
Recommendation 14 That CCNFSDU agree to revise the minimum and GUL for manganese as follows: **Manganese** **Unit** / **Minimum** / **Maximum** / **GUL** µg /100 kcal / [1] / - / [100] µg /100 kJ / [0.24] / - / [24]	Colombia apoya la propuesta de los valores mínimos y de GUL para el manganeso.
Recommendation 15 That CCNFSDU agree to revise the minimum and GUL for iodine, as follows: **Iodine** **Unit** / **Minimum** / **Maximum** / **GUL** µg /100 kcal / [10] / - / [60] µg /100 kJ / [2.4] / - / [14.3]	Colombia está de acuerdo con los valores mínimos y de GUL propuestos para el Yodo, sin embargo en el GUL propone ajustar de [14.3] a [14], tal como se encuentra en el CODEX STAN 72-1981.
Recommendation 16 That CCNFSDU agree to establish a minimum and GUL for selenium as follows: **Selenium** **Unit** / **Minimum** / **Maximum** / **GUL** µg /100 kcal / [2] / - / [9] µg /100 kJ / [0.48] / - / [2.2]	Colombia apoya la propuesta de los valores mínimos y de GUL para el selenio.
Recommendation 17 That CCNFSDU agree to revise the minimum and GUL for copper as follows: **Copper19)** **Unit** / **Minimum** / **Maximum** / **GUL** µg /100 kcal / [35] / - / [120] µg /100 kJ / [8.4] / - / [29] [19) Adjustment may be needed in these levels for infant formula made in regions with a high content of copper in the water supply.]	Colombia está de acuerdo con el valor mínimo propuesto para el cobre, y mantiene su posición del GET para el GUL de [250] µg/100 kcal basado en el contenido de cobre en la leche humana.
Recommendation 18 That CCNFSDU agree to revise the minimum and GUL for zinc as follows: **Zinc20)**	Colombia está de acuerdo con el valor mínimo propuesto para el zinc, y mantiene su posición del GET para el GUL de [1.5] µg/100

Recomendación	Posición Colombia
Unit / **Minimum** / **Maximum** / **GUL** µg /100 kcal / [0.5] / - / [1.0] µg /100 kJ / [0.12] / - / [0.24] [20) For Follow-up formula based on soy protein isolate 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.]	kcal basados en el CODEX STAN 72-1981.
Recommendation 19 It is the recommendation of the Chairs that choline be included in the Optional Ingredients section of the *Standard for Follow-up Formula* for product for older infants with the following specifications: **Choline** **Unit** / **Minimum** / **Maximum** / **GUL** mg /100 kcal / [-] / - / [150] mg /100 kJ / [-] / - / [36]	Colombia está de acuerdo con la propuesta de incluir al colina, como ingrediente opcional en el *Standard for Follow-up Formula* y con los valores propuestos.
Recommendation 20 It is the recommendation of the Chairs that myo-inositol be included in the Optional Ingredients section of the *Standard for Follow-up Formula* (for product for older infants) with the following specifications: **Myo-inositol** **Unit** / **Minimum** / **Maximum** / **GUL** mg/100 kcal / [-] / - / [40] mg /100 kJ / [-] / - / [9.6]	Colombia está de acuerdo con la propuesta de incluir al myo-inositol, como ingrediente opcional en el *Standard for Follow-up Formula* y con los valores propuestos.
Recommendation 21 It is the recommendation of the Chairs that L-carnitine be included in the Optional Ingredients section of the *Standard for Follow-up Formula* for product for older infants. As majority support is for not setting a minimum or GUL, the Chairs propose following a similar approach to that used for expressing the permission for the optional addition of total nucleotides. The proposed specification for consideration is presented below: **L-Carnitine** Levels may need to be determined by national authorities.	Colombia está de acuerdo con la propuesta de incluir al L- carnitina, como ingrediente opcional en el *Standard for Follow-up Formula* y que los valores necesarios sean determinados por las autoridades nacionales.
Recommendation 22 As a result of the collective comments of the eWG, the Chairs propose the following amended drafting for consideration. As discussed in the previous section, the Chairs are also proposing that choline, myo- inositol, and L-carnitine be included as optional ingredients, they have therefore been added in the below section.	De acuerdo con las anteriores recomendaciones, Colombia apoya que la colina, inositol miocardio, y la L-carnitina se incluye como ingredientes opcionales, y por lo tanto, han sido añadidas en la sección de ingredientes opcionales.

3. Colombia propone las siguientes modificaciones en la sección de ingredientes opcionales:

3.3.2 **Optional Ingredients**

3.3.2.1 *In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients [**or substances**] may be added* **<u>to ensure that</u>** *the product is suitable to form part of a [**progressively diversified diet**] intended for use [**by older infants**].*

3.3.2.2 **[The suitability for the particular nutritional use in products for older infants (6-12 months) shall be demonstrated as part of a complementary feeding diet; the safety of these ingredients/ substances shall be scientifically demonstrated at the level of use.]**

3.3.2.3 [*The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the Follow-up Formula ready for consumption shall not exceed the levels listed below. This is not intended to be an exhaustive list, but provides a guide for national authorities as to appropriate levels when these substances are added].*

Taurine

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	12	-
mg/100 kJ	-	3	-

Total nucleotides

Levels may need to be determined by national authorities.

Docosahexaenoic Acid[20)]

Unit	Minimum	Maximum	GUL
% of fatty acids	-	-	0.5

Para los valores de DHA, ARA y EPA, Colombia considera que:
Se reitera que la adición de DHA debe ser opcional y no debe ser dependiente de ARA y/o EPA; es decir, si se adiciona DHA no es necesario adicionar ni ARA ni EPA. En cambio sí se adiciona ARA se requiere la misma cantidad de DHA y si se adiciona EPA no deberá exceder la cantidad de DHA. Y proponene modificar la nota al pie así:

20) The ARA and EPA addition is optional and not required when DHA is added. However If ARA were to be added then its content should reach at least the same concentration as DHA. If EPA were to be added its content should not exceed the content of DHA.

PREPARADOS COMPLEMENTARIOS PARA NIÑOS PEQUEÑOS (12 - 36 MESES)

Colombia reitera su posición para tener requisitos nutricionales específicos para el rango de 12 - 36 meses, que sean resultado de investigaciones de algún RABs.

ECUADOR

English:

General comments:

Ecuador agrees to the consensus within the Committee that follow-up formula should be regulated to ensure safety, quality and integrity of those products which are traded internationally.

Moreover, the role of follow up formula differs between older infants and young children due to the diet of young children is more diverse than older infants, then, it would be useful to prepare two separate documents of standard for follow up formula, one with criteria for older infants and other one with criteria for young children.

Specific comments:

Section 2
2. DESCRIPTION
2.1 Product definition
2.1.2 Follow-up formula:
2.1.2 Formulas de seguimiento:

Ecuador agrees to the use of the **first** option:
"Follow-up formula is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold"

Even though Ecuador agrees to the proposed paragraph, Ecuador considers that it would be important to include: ...distribution and "sale" in order to ensure the compliance of the conditions during the sale phase.

2.2 Other definitions
Ecuador agrees to the sections 2.2.1-2.2.3

3. ESSENTIAL COMPOSITION AND QUALIFY FACTORS (for older infants 6-12 months)
3.1 Essential composition
3.1.1 Follow-up formula
Ecuador agrees to the following option:

Follow-up formula is a **product** consisting of milk of cows or other animals or a mixture thereof**,** and/or other ingredients which have been **proved to be suitable to support growth and development for the older infants and young children.**

Ecuador agrees to the **first** option:
The nutritional safety and adequacy of follow-up formula shall be scientifically demonstrated to support growth and development of older infants and young children.

Rationale:
Ecuador considers that it should be used "**products**" instead of "food" due to the word "food" might promote the consumption of follow up formula because if the products is labeled as "food"consumers might unintentionally associate this product (the follow up formula) with non-procesed food.

On the other hand, Ecuador suggests to not use the phrase "nutritionally adecuate" even though when the product is nutritionally balanced, because the message might be missunderstood by the consumers, and, they might replace their natural food by the follow-up formula.

Finally, Ecuador agrees to the use of the first option of statement due to, the second option promotes the consumption of follow up formula products.

3.3.2 Optional ingredients
3.3.2.1
*Ecuador agrees to the **second** option:*
In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients may be added to the follow-up formula for older infants where the safety and suitability of the optional ingredient, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.
Rationale
The first option might promote the consumption of follow up formulas with the phrase: "suitable to form part of a progressively diversified diet or (the complementary diet)". The approach of the second option is about the safety of the ingredients rather than a consumption approach.

Español:
Comentarios generales:
Ecuador está de acuerdo con lo consensuado en el Comité, respecto a que los preparados complementarios deben estar regulados para garantizar la seguridad, calidad e integridad de esos productos los cuales se comercializan internacionalmente.

Además, el rol de los preparados complementarios es diferente para lactantes de más edad (6 a 12 meses de edad) y niños pequeños (12 a 36 meses de edad) debido a que la dieta de los niños pequeños es más

diversa que la de los lactantes, así, sería muy útil el preparar dos documentos por separado de norma para preparados complementarios, uno con criterios para lactantes, y otra con criterios para niños pequeños.

Comentarios específicos

Sección 2
2. DESCRIPCION
2.1 Descripción del producto
2.1.2. Fórmulas de seguimiento

Ecuador está de acuerdo con la **primera** opción propuesta:
Los preparados complementarios se elaboran exclusivamente por medios físicos y se envasan de forma que prevenga el derramamiento y contaminación en condiciones normales de manipulación, almacenamiento y distribución en el país donde el producto es vendido.

Aun cuando Ecuador está de acuerdo con el párrafo propuesto, Ecuador considera que sería importante incluir:…distribución y "venta" a fin de asegurar el cumplimiento de las condiciones durante la etapa de venta.

2.2 Otras definiciones
Ecuador está de acuerdo con las secciones 2.2.1-2.2.3

3. Composición esencial y características de calidad (para lactantes de mas edad 6-12 meses)
3.1 Composición esencial
3.1.1 Formula de seguimiento

Ecuador está de acuerdo con la siguiente opción propuesta:
Preparado complementario es el producto que consiste en leche de vaca u otros animales, o una mezcla de los mismos, y/u otros ingredientes que se han demostrado ser adecuados para favorecer el crecimiento y desarrollo de los lactantes y niños pequeños.

Ecuador está de acuerdo con la **primera** opción propuesta:
La seguridad nutricional e idoneidad de los preparados complementarios deberán estar científicamente demostrado para favorecer el crecimiento y desarrollo de los lactantes de más edad y niños pequeños.
Justificación:
Ecuador considera que se debería usar el término "productos" en lugar del término "alimentos", ya que la palabra "alimento" podría promover el consumo de preparados complementarios, porque si el producto es rotulado como "alimento" los consumidores podrían involuntariamente asociar las preparados complementarios con productos no procesados.

Por otra parte, Ecuador sugiere no utilizar la frase "nutricionalmente adecuado" aun cuando el producto es nutricionalmente balanceado, porque el mensaje puede ser mal interpretado por los consumidores, y, ellos podrían reemplazar su alimentación natural por los preparados complementarios.

Finalmente, Ecuador esta de acuerdo con el uso de la primera opción del párrafo debido a que la segunda opción promueve el consumo de preparados complementarios.

3.3.2 Ingredientes opcionales
3.3.2.1
Ecuador está de acuerdo con la **segunda** opción:
Además de los requisitos de composición indicados en 3.2.4 a 3.2.6, otros ingredientes podrían añadirse a los preparados complementarios para lactantes de más edad, en los cuales la seguridad e idoneidad del ingrediente opcional, según el nivel de uso, es evaluado y demostrado con evidencia científica aceptada.
Justificación
La primera opción podría promover el consumo de preparados complementarios por la frase: "Adecuado para formar parte de una dieta progresivamente diversificada o (dieta complementaria)". El enfoque de la

segunda opción es acerca de la seguridad de los ingredientes más que de un enfoque de consumo.

EUROPEAN UNION

European Union competence
European Union vote

The European Union (EU) would like to thank New Zealand, France and Indonesia for their work on document CX/NFSDU 15/37/5. On the basis of the on-going discussions in the EU on follow-up formula, the EU would like to offer the following preliminary comments.

GENERAL COMMENTS

On follow-up formula for older infants

The EU is of the view that the compositional requirements for follow-up formula for older infants should be consistent with those for infant formula unless differences are scientifically justified (e.g. iron levels). The EU is also of the view that the current revision of the compositional requirements of follow-up formula for older infants should take into account the most recent, relevant, scientific information available. In this respect, the EU would like to point to the Scientific Opinion of the European Food Safety Authority on the essential composition of infant and follow-on formulae which was issued last year (2014)[1]. This is the most recent systematic advice by a Codex recognized authoritative scientific body (RASB) on the composition of infant formula and follow-up formula for older infants.

In line with our preference for consistency in the compositional requirements for follow-up formula for older infants and those for infant formula, the EU considers that once agreement is reached in CCNFSDU on the compositional requirements for follow-up formula for older infants, efforts should be undertaken to ensure that the compositional requirements for infant formula are based on the same datasets used for follow-up formula for older infants. Such efforts should aim to a targeted revision of section 3 of CODEX Standard 72-1981 on Infant Formula and Formulas for special medical purposes intended for infants. It is important to underline that this targeted revision would be based on the agreed compositional requirements for follow-up formula for older infants - with scientifically justified differences as appropriate – and would not open other sections of the Infant Formula Standard.

On follow-up formula for young children

Bearing in mind previous discussions in CCNFSDU and in the relevant eWGs, the EU finds the approach proposed by the Chairs sensible and considers that it merits further consideration in CCNFSDU. In our view, this takes into account the difficulty to lay down specific compositional rules for follow-up formula for young children *per se*, and regional variability with respect to nutrients of concerns. Furthermore, it is in line with the scientific advice of EFSA (2014) whereby, "*formulae consumed during the first year of life can continue to be used by young children"* and with the consideration that the increased consumption of other foods in the diet of young children makes it unnecessary to require follow-up formula for young children to comply with all the requirements for follow-up formula for older infants.

The EU is of the view that if minimum compositional requirements are to be set for follow-up formulae for young children, the main focus should be on those nutrients whose consumption is inadequate on a global scale. This is all the more valid, given that, in any case, the eWG Chairs propose to leave to the discretion of national authorities the mandatory addition of other nutrients to meet the specific needs of their population.

In this context, the EU notices that there is no known global inadequate intake on a global scale for some of the listed nutrients proposed by the eWG Chairs for mandatory addition. The EU would therefore like to seek further clarification on the rationale underpinning the proposed nutrients.

SPECIFIC COMMENTS

The EU has a number of suggestions for re-drafting to the text as indicated below.

Section 2, paragraph 2.1.1

[1] http://www.efsa.europa.eu/fr/efsajournal/doc/3760.pdf

The following redrafting is proposed:

2.1.1 Follow-up formula means a food intended for use as ~~a liquid part of the weaning diet for the infant from the 6th month on and for young children.~~

~~[~~a) the **a** liquid part of the **progressively diversified** diet for ~~older~~ infants**,** when complementary feeding is introduced~~;~~**,** and
~~b) a liquid part of the progressively diversified diet of~~ **for** young children.~~]~~

Rationale:
The EU is of the view that follow-up formula for older infants (6-12 months) and young children (12-36 months) are conceptually similar: they are liquid elements in the diversified diet of older infants and young children. For this reason the EU wonders whether the text proposed by the eWG Chairs, which lists two different product categories under letters (a) and (b), would give an unnecessary and unjustified recognition to the difference between the two product categories. The EU would support a broad and simpler definition for follow-up formula, similar to the one present in the current Standard, which would also avoid repetitions.

The EU would, in addition, like to note that there is no reason to qualify infants as "older", given that a reference to introduction of complementary feeding is included.

Section 2, paragraph 2.1.2

The following redrafting is proposed:

~~[~~Follow-up formula is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold~~]~~.

~~OR~~

~~[Follow-up formula is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage [,] and distribution [and sale] in the country where the product is sold].~~

Rationale:
The EU would support the first option presented in document CX/NFSDU 15/37/5, which mirrors the existing wording of point 2.1.2 of the Infant Formula Standard. The EU would like to seek clarification on the rationale for the changes proposed in the second option, and on why these should be relevant for follow-up formula and not for infant formula.

Section 2, paragraph 2.2.2

The following redrafting is proposed:

~~2.2.2 [Older infants means persons from the age of 6 months and not more than 12 months of age.]~~

Rationale:
The EU is of the view that there is no need to introduce a definition of "older infant" given that the definition proposed specifically refers to the introduction of complementary feeding.

Section 2, paragraph 2.2.3

A minor editorial is proposed:

2.2.3 The term young child means **a** person~~s~~ from the age of more than 12 months up to the age of three years (36 months).

Section 3, paragraph, 3.1.1

The following redrafting is proposed:

3.1.1 Follow-up formula is a ~~[food] OR [~~product~~] prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, [~~based on~~] OR [consisting of]~~ milk of cows or other animals or a mixture thereof ~~[,]~~ and/or other ingredients which have been ~~[proved] OR [~~proven~~]~~ to be ~~[safe and]~~ suitable **for the feeding of infants, after the introduction of complementary feeding, and for young children.** ~~[and nutritionally adequate] [to support growth and development] for [the intended age range] OR [older infants and young children]. infants from the 6th month on and for young children. [~~The nutritional safety and adequacy of follow-up formula shall be scientifically demonstrated to support growth and development of ~~older~~ infants **after the introduction of complementary feeding** and young children.~~]~~

~~OR~~

~~[Consumption of the formula should appropriately contribute to normal growth and development of the intended age range].~~

Rationale:
The EU is of the view that the requirement under consideration should follow as much as possible the one established in the Infant Formula Standard (with adjustments where necessary).

In particular, the EU proposes deletion of the comma after the word "*thereof*". The reason for this is to ensure that the suitability requirement in the definition applies to both "*other ingredients*" and "*milk of cows or other animals or a mixture thereof*". In order to protect the health of infants and young children, it is important to ensure that all ingredients of formulae are suitable, including the animal protein source.

INDIA

General Comment:

India suggests inclusion of WHA resolution 39.28 that is “Follow-up formula is not necessary for the growth and development of young children for the age of 12 months to 36 months” and also “The World Health Organization recommends exclusive breastfeeding for the first six months, with safe and appropriate complementary foods thereafter and continued breastfeeding up to two years or beyond” within the standard.

Specific Comment:

Section 2: Description
2.1 Definitions:
2.1.1 Follow-up Formula

The text may be modified as under:
Follow-up formula means a food intended for use as a component of the Complementary foods.

Recommendation 3
Protein
India proposes to retain the proposed minimum (1.8 g/100 kcal) and suggests maintaining the existing maximum levels (5.5 g/100 kcal) of Proteins.

Rationale: Any decrease in the maximum levels of Proteins will lead to substitution by the other Carbohydrate/ starches which have poor nutritive value. National/ regional authorities can fix up maximum as per their requirements.

Recommendation 7
Total Carbohydrate

Footnote9: India proposes the Carbohydrate ingredient should be lactose and no Glucose polymers (sucrose, fructose, Corn Syrup, maltodextrin and starches) should be permitted in the standard as these leads to NCD risks.

Section 3.3.3 Optional Ingredients:

India proposes that the optional ingredients; Taurine, DHA, ARA, EPA, Choline, myo-inositol and L-Carnitine should not be added in the standard.

Rationale: The use of optional ingredients should not be permitted. If an ingredient is deemed to be necessary it must be in all products. There is no justification given in the standard for adding optional ingredients. Moreover, these ingredients are used as food additives which may increase the levels of contaminants in the Follow up formula products. Also, they become a source of unsubstantiated health claims for inappropriate promotion of the products.

6.4.7 Zinc
Recommendation 18:

The unit provided in the document is µg. It should be replaced with mg.

The text will be amended as under:

Zinc	
Unit	Minimum
~~µg~~ mg/100kcal	0.5
~~µg~~ mg/100kj	0.12

Rationale: typo-graphical error.

KENYA

Issue: Description

2.1.1 Follow-up formula means a food intended for use as ~~a liquid part of the weaning diet for the infant from the 6th month on and for young children.~~
[a) the liquid part of the diet for older infants when complementary feeding is introduced; and
b) a liquid part of the progressively diversified diet of young children.]

Position: We propose the following change to the definition that *'Follow-up formula means a food that may be used by older infants when complementary food is introduced and by young children'*

2.1.2 [Follow-up formula is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold].
OR
[Follow-up formula is so processed ~~by physical means only~~ and ~~so~~ packaged as to prevent spoilage and contamination under all normal conditions of handling, storage [,] ~~and~~ distribution [and sale] ~~in the country where the product is sold~~].

Position: Supports adoption of first option. This is because as a result of the vulnerability of the targeted age group, their products should be only processed by physical means only and not any other such as chemical or a combination of physical and any other processing technique.

Recommendations 1 – 22: Nutrient composition for follow-up formula for the age 6 – 12 months

Position: We support adoption of all nutrients aligned to the Codex Standard for infant formula and where there is deviation such as in Iron, the levels provided in infant formula should be adopted.

MALAYSIA

2.1.1 **Follow-up formula** means a food intended for use as ~~a liquid part of the weaning diet for the infant from the 6th month on and for young children.~~
[a) the liquid part of the diet for older infants when complementary feeding is introduced; and
b) a liquid part of the progressively diversified diet of young children.]

Malaysia's Comment:
Malaysia does not support to include part (b) in the product definition of follow-up formula. This is in line with our consistent position that Malaysia supports the development of 2 separate product categories, with a point differentiation at 12 months, ie a food for older infants 6-12 months and a separate food for young children 12-36 months group.

The rationales for this proposal, as has been stated during the electronic working group discussions, are as follows:

a. The nutritional requirements of older infants and young children are different
b. The feeding pattern for older infants and young children are also different. The older infants take small to moderate amount of weaning diet, and milk is still very much a main source of nutrition. Follow-up formulas should be nutritionally adequate to meet these needs. Young children, on the other hand, generally eat family foods, while milk is a wholesome addition to the child's regular diet.
c. There are differences in the activity, physiological, growth and development pattern between older infants and young children.

Recognizing that milk is still be a required and wholesome food for growing children in addition to family food, Malaysia proposes that a milk product should be made available for young children above 1 year of age and should be distinctly different in term of labelling. Therefore, Malaysia would like to propose two separate product categories which are:

i) 6-12 months : Follow-up Formula
ii) 12-36 months : to be labelled as Milk Powder for Children or other similar terminology

It would be more logical, more useful and less confusing to the consumer if there are two separate products, with distinctly different nutrient composition and clearly labeled. The definition for a follow-up formula should therefore be clearly focused only on older infants.

2.1.2 **[Follow-up formula** is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold].

OR

~~**[Follow-up formula** is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage [,] and distribution [and sale] in the country where the product is sold].~~

Malaysia's Comment:
Malaysia agrees with Option 1 which is the same text used in current Standard for Infant Formula and Formulas for Special Medical Purpose Intended for Infants (CODEX STAN 72-1981).

2.2.2 [**Older infants** means persons from the age of 6 months and not more than 12 months of age.]

Malaysia's Comment:
Malaysia agrees to include the definition of older infants in the standard.

3.1.1 Follow-up formula *is a [food] OR [product]* ~~*prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin,*~~ *[based on] OR [consisting of] milk of cows or other animals or a mixture thereof [,] and/or other ingredients which have been [proved] OR [proven] to be [safe and] suitable [and nutritionally adequate] [to support growth and development] for [the intended age range] OR [older infants and young children].* ~~*infants from the 6th month on and for young children.*~~

Malaysia's Comment:
Malaysia proposes that the essential composition in the paragraph 3.1.1 be as follows:

> ***3.1.1 Follow-up formula*** *is a* ~~*[*~~*food*~~*]*~~ ~~*OR [product]*~~ ~~*[*~~*based on*~~*]*~~ ~~*OR [consisting of]*~~ *milk of cows or other animals or a mixture thereof* ~~*[,]*~~ *and/or other ingredients which have been* ~~*[proved] OR [*~~*proven*~~*]*~~ *to be* ~~*[*~~*safe and*~~*]*~~ ~~*suitable*~~ ~~*[*~~*and nutritionally adequate*~~*]*~~ ~~*[*~~*to support growth and development*~~*]*~~ *for* ~~*[*~~*the intended age range*~~*]*~~ ~~*OR [older infants and young children].*~~

[The nutritional safety and adequacy of follow-up formula shall be scientifically demonstrated to support growth and development of older infants and young children.]

OR

~~*[Consumption of the formula should appropriately contribute to normal growth and development of the intended age range].*~~

Malaysia's Comment:
Malaysia prefers Option 1 which is the same text used in current Standard for Infant Formula and Formulas for Special Medical Purpose Intended for Infants (CODEX STAN 72-1981).

3.3.2 **Optional Ingredients**

~~3.3.2.1 *In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients [**or substances**] may be added when required to ensure that the product [provided the product] is [**safe and**] suitable to form part of a [**progressively diversified diet**] OR [**the complementary diet**] intended for use [**from 6th months on**] OR [**from the age of 6 months/from 6 months of age**] OR [**by older infants**].*~~

OR

[In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.]

Malaysia's Comment:
Malaysia supports Option 2.

~~3.3.2.2 The usefulness of these nutrients shall be scientifically shown. *[The suitability for the particular nutritional uses [**in products for**] of [**older**] infants and the safety of these [**ingredients and**] substances shall be scientifically demonstrated. [**When any of these ingredients or substances is added**] T the formula shall contain sufficient amounts of these substances to achieve the intended effect, taking into account levels in human milk.]*~~

OR

[When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect OR *benefit, ~~[taking into account levels in human milk].]~~*

Malaysia's Comment:
Malaysia supports Option 2 but proposes to delete [taking into account levels in human milk] because the food under discussion is follow-up formula where the older infant consumes this formula as well as complementary food.

MEXICO

English:

GENERAL COMMENTS

According to recommendations of the World Health Organization, infants during their first six months of age must be fed exclusively with breast-milk for optimal growth and development and good health. After that period, in order to meet their nutritional requirements, infants must receive complementary foods nutritionally adequate and safe, maintaining breast-feeding until two years of age or beyond.

As a consequence breast-feeding is a feeding period during infants and young children life, which is not segmented.

In this sense, any formula used for infant feeding should be considered as a breast-milk substitute.

In addition to this and due to its composition, infant formula as a breast-milk substitute, could be consumed by infants from 6-12 months of age and even by young children as a part of their diet, without requiring any significant modifications to the levels of nutrients as they are established in the CODEX-STAN 72-1981. This as it is indicated in the document, because it is presumed that from six months, contribution of complementary foods to energy and nutrient intakes compensate the higher dietary requirements of older infants.

Even STAN 72 contemplates this situation implicitly in 9.6.4: *Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six month,* which confirms the use of infant formula in this period of life (0-12 months).

While the terms of reference for the electronic working group were established to continue working on a Standard for follow-up formula, in this order of ideas, we reiterate the position consistent in supporting the existence of a sole formula destined to be used for the feeding of infants from 0 to 12 months, regulated through the Standard for Infant Formula and Formulas for Special Medical Purposes intended for Infants (CODEX-STAN 72-1981), where defined specifications on nutrient composition remain the same for the product destined to be consumed by infants in the whole period of age.

This is also supported on the fact that majority of recommendations derived from the electronic working group are oriented to the alignment of specifications of nutrient composition to those described in STAN 72 for infant formula. This suggests that the formulated product has the same characteristics that the formula destined to infants from 0-6 months plus what was concluded in previous work of the electronic working groups the role in the diet is more similar to the role that they have during the first months of age as a breast-milk substitute.

While it is recognized that composition requirements for some nutrients are always subject to revision according to the latest scientific evidence, this possible changes could also be applicable to infants from 0-6 months.

Additionally if differences exists, for example because of matters associated to the metabolism of older infants, which may suggests more flexibility on the requirements, if these are consider significant could be made within the same STAN 72.

PRODUCT FOR CHILDREN 12-36 MONTHS

Regarding the product directed to young children, we agree with the opinion that these products don't have a sole role in providing the critical nutrients, therefore, they cannot be considered essential to satisfy the requirements of young children, but they are part of the diet as any other food.

In this sense the proposed approach with respect to the mandatory addition of some nutrients should consider an integral and case by case assessment for each nutrient. That is to say that when we think of a product that may provide certain nutrients such as those presented, the presence of some of them in the product (such as iron), at least nutritionally, which can limit or facilitate absorption of other (as synergistic or antagonistic agents) must therefore be considered.

Additionally the decision of national authorities is an essential element in the definition of nutrients, levels and vehicles in which those nutrients, for which it is determined that there are difficulties in meeting the requirements in this age group, must be added as mandatory.

Finally, it is important to mention that in the framework of Codex there is orientation that could be considered, such as the General Principles for the Addition of Essential Nutrients to Foods CAC/GL 9-1987 that could support the decision on the addition of specific nutrients.

SPECIFIC COMMENTS

EWG RECOMMENDATIONS	COMMENTS FROM MEXICO
2. DESCRIPTION 2.1 Product Definition 2.1.1 **Follow-up formula** means a food intended for use as ~~a liquid part of the weaning diet for the infant from the 6th month on and for young children.~~ [a) the liquid part of the diet for older infants when complementary feeding is introduced; and b) a liquid part of the progressively diversified diet of young children.]	See General Comments. It is noted that the proposed definition for the product for children 6-12 months could be associated with the role of a breast-milk substitute since the main liquid part of the diet of older infants, even when complementary feeding is introduced, must continue to be breast-milk. In this sense the product that we are trying to

	define could be considered within the definition of an infant formula as established in the STAN 72, with the understanding that although it indicates that is specially formulated to satisfy by itself the nutritional requirements of infants during the first months of life, this formulation as a substitute means that it can continue to be consumed by older infants given that, as indicated in the document, it is assumed that after six months the contribution to energy and nutrient intake of complementary foods compensates the higher dietary needs of older infants. Therefore the definition proposed in the STAN 72 would read: **Infant formula** means a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life **and preponderantly after the timely introduction of complementary feeding.** (Proposed amendment to Definition from STAN 72)

Español:

COMENTARIOS GENERALES

Conforme a las recomendaciones de la Organización Mundial de la Salud, los lactantes durante los seis primeros meses de vida deben ser alimentados exclusivamente con leche materna para lograr un crecimiento y un desarrollo óptimo y un buen estado de salud. Posteriormente, a fin de satisfacer los requerimientos nutrimentales, los lactantes deben recibir alimentos complementarios nutrimentalmente adecuados e inocuos manteniendo la lactancia materna hasta los dos años de edad o más.

En consecuencia la lactancia materna es un período de alimentación en la vida de los lactantes y de los niños de corta edad, el cual no se segmenta.

En este sentido, cualquier fórmula utilizada para la alimentación del lactante debería ser considerada como un sucedáneo de la leche materna.

Aunado a esto y dada su composición, la fórmula para lactantes como sucedáneo de leche materna, puede ser consumida por los lactantes de 6 a 12 meses e incluso niños de corta edad como parte de la dieta, sin requerir modificaciones significativas a las cantidades de nutrimentos con respecto a lo actualmente dispuesto en el CODEX-STAN 72-1981) . Esto dado que como se indica en el documento, se presume que a partir de los seis meses, la contribución a la ingesta energética y de nutrimentos de los alimentos complementarios compensa las mayores necesidades dietéticas de los lactantes de más edad.

El mismo STAN 72 contempla esta situación de manera implícita con lo que dispone en su numeral 9.6.4: *incluir en la etiqueta la indicación que a los lactantes tendrán que dárseles alimentos complementarios, además de la fórmula, a partir de una edad que sea apropiada para su crecimiento específico y necesidades de desarrollo, según las recomendaciones de un trabajador sanitario independiente y en cualquier caso a partir de los seis meses de edad,* situación que confirma el uso de la fórmula para lactantes en este período de vida (de 0 a 12 meses de edad).

Si bien los términos de referencia para el grupo de trabajo electrónico se establecieron para continuar trabajando sobre una Norma para fórmulas de continuación, en este orden de ideas, reiteramos la posición consistente en apoyar únicamente la existencia de una fórmula destinada a ser utilizada en la alimentación de los lactantes de 0 a 12 meses, regulada a través de la Norma para Preparados para Lactantes y Preparados para usos medicinales especiales destinados a los lactantes (CODEX-STAN 72-1981), en donde las especificaciones de composición nutrimental definidas sean las mismas para el producto destinado para ser consumidos por lactantes en todo este intervalo de edad.

Esto se apoya además en que la mayoría de las recomendaciones derivadas del grupo de trabajo electrónico se orientan a la alineación de las especificaciones de composición nutrimental con aquellas descritas en el STAN 72 sobre fórmulas para lactantes. Esto sugiere que el producto formulado tiene las mismas características que la fórmula destinada a los lactantes de 0 a 6 meses aunado a que como se vio en conclusiones previas del grupo electrónico el rol en la dieta es mucho más similar al rol que cumplen en los primeros meses como sucedáneo de leche materna.

Si bien se reconoce que los requisitos de composición de ciertos nutrimentos siempre están sujetos a revisión de acuerdo a la evidencia científica más reciente, las posibles modificaciones en los mismos también podrían aplicar a los lactantes de 0-6 meses.

Adicionalmente de existir diferencias, por ejemplo por cuestiones asociadas al metabolismo de los lactantes mayores, que pudieran sugerir mayor flexibilidad en los requisitos, de considerarse significativo podrían acotarse en la misma norma 72.

PRODUCTO PARA NIÑOS DE 12-36 MESES

En el caso del producto dirigido a niños de corta edad coincidimos con la opinión de que estos no tienen un rol único en la provisión de los nutrimentos críticos; por lo tanto, no pueden ser considerados indispensables para satisfacer los requerimientos de los niños de corta edad, sino que son parte de una dieta al igual que cualquier otro alimento.

En este sentido el enfoque propuesto sobre la adición obligatoria de ciertos nutrimentos debería considerar una evaluación integral y caso por caso para cada nutrimento. Es decir, que al momento de pensar en un producto que aporte ciertos nutrimentos como los presentados, debe en consecuencia considerarse que la presencia de algunos de ellos en el mismo producto (ejemplo hierro), al menos en términos nutricionales, puede limitar o facilitar la absorción de otro, actuando como agentes sinérgicos o antagónicos.

Adicionalmente la potestad de las autoridades nacionales es un elemento fundamental en la definición de los nutrimentos, sus niveles y vehículos en los que se deberán añadir obligatoriamente aquellos nutrimentos para los que se determine que hay dificultades para alcanzar los requerimientos en este grupo de edad.

Por último es importante mencionar que en el marco del Codex se cuenta con orientación que se podría considerar como son los Principios Generales para la adición de nutrientes esenciales a los alimentos CAC/GL 9-1987 que pudiera apoyar la decisión sobre la adición de nutrientes específicos.

COMENTARIOS PARTICULARES

RECOMENDACIONES DEL EWG	COMENTARIOS DE MEXICO
2. DESCRIPCIÓN 2.1 Definición del producto 2.1.1 Por **preparados complementarios** se entiende todo alimento destinado a ser utilizado como ~~parte líquida de una ración de destete para lactantes a partir del sexto mes y para los niños pequeños.~~ [a) la parte líquida del régimen alimentario de los lactantes de más edad cuando se introduce la alimentación complementaria; y b) parte líquida del régimen alimentario progresivamente diversificado de los niños pequeños.]	Ver Comentarios Generales. Se observa que la definición propuesta para el producto dirigido a los niños de 6-12 meses podría asociarse con el rol de un sucedáneo de leche materna en virtud de que la parte líquida principal del régimen alimentario de los lactantes de más edad aun cuando se empiece a introducir la alimentación complementaria debe continuar siendo la leche materna. En este sentido el producto que se intenta definir podría ubicarse dentro de la definición de una fórmula para lactantes conforme a lo establecido en el STAN 72, entendiendo que si bien la misma indica que está especialmente formulado para satisfacer por si sólo las necesidades nutricionales de los lactantes durante los primeros meses de vida, esta formulación como sucedáneo implica que puede seguir siendo consumida por lactantes mayores dado que como se indica en el documento se presume que a partir de los seis meses, la contribución a la ingesta energética y de nutrientes de los alimentos complementarios

	compensa las mayores necesidades dietéticas de los lactantes de más edad. Por lo tanto la definición propuesta en el STAN 72 quedaría como sigue: **Fórmulas para lactantes**: sucedáneo de la leche materna especialmente fabricado para satisfacer, por sí solo las necesidades nutrimentales de los lactantes durante los primeros meses de vida **y de manera preponderante después de la introducción oportuna de la alimentación complementaria**.(Definición tomada de la STAN 72 y que en su momento se propondría su modificación).

VIETNAM

GENERAL COMMENTS

Vietnam supports the proposed draft revision to the Standard for Follow up Formula which presented in Appendix 2 with some comments as follows:

1. Section 2.1.1. Definition:
Vietnam suggests to retain the term "*weaning diet*" in the current definition to make clear that it is not a breastmilk substitute. The suggested definition is:

2.1.1. Follow up formula means a food intended for use as a liquid part of the weaning diet for:
- a] older infant when complementary feeding is introduced; and
- b] young children as a part of the progressively diversified diet.

2. Section 3.1.3 Protein
Vietnam support the minimum and maximum level of **Protein at 1.8 – 3.5 g/100 kcal as suggested in the PROPOSED DRAFT REVISION TO THE *STANDARD FOR FOLLOW-UP FORMULA.***

3. Section 6.3.1. Vitamin A
Vietnam suggests to retain the current maximum level of **Vitamin A at 225 µg RE/100kcal**, considering the high rate of Vitamin A deficiency in Vietnam and some other region in the world, and the history of apparent safe use of the current level.

4. Section 6.3.2. Vitamin D
Vietnam suggests the maximum level of **Vitamin D is 4.5 µg/100kcal**, considering the high rate of Vitamin D deficiency in Vietnam and some other region in the world, and vitamin D's importance in the diet.

5. Section 6.4.7. Zinc
Vietnam suggests the GUL level of Zinc is **1.5 µg/100kcal**, considering 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.

IBFAN - International Baby Food Action Network

General Comment:

1. The protection of "consumer" health is a key mandate for Codex that is especially relevant for any discussion about the continued need for a separate standard for an industrial milk product that will be marketed to replace breastmilk during the critical stages of health, development and growth.
2. The adoption of the Follow-on Formula standard in 1987 is universally acknowledged by health advocates to be a mistake that has been used to establish and expand a market for unnecessary,

risky products to the detriment of child health. It has undermined the adoption and maintenance of strong marketing regulations based on the International Code and Resolutions.

3. IBFAN has noted that the lack of consensus and the lack of agreement in comments submitted to the FUF Working Group is not fully reflected in the reports submitted by the chairs.
4. The report acknowledges on Page 4 that the majority of the eWG members consider that there needs to be a discussion about the need for these products. The Chair's decision to defer such discussion, risks compromising the safeguards necessary to protect young child health.
5. The lack of necessity for these products was noted by a number of member states and by the representative of the WHO, who highlighted the critical importance of the World Health Assembly Resolution 39:28 in order to safeguard the health, growth and development of older infants and young children. . Follow-on formulas are industrial milk products that will be marketed to replace breastmilk.
6. The age of introduction of follow-on formula is reported to be from the age of six months. The preference of a considerable number of member states and observer organizations for the 12 months introduction and for FUF to be included in a renamed infant formula standard as an Annex or footnote - has consistently been ignored. Indeed there is no need for an upper cut-off age beyond 12 months. Since the composition of Follow-on Formula differs from Infant formula in very few places – such a move would help ensure the safety and marketing of these products is in line with the recommendations of the World Health Assembly.
7. The compositional requirements could be readily met by the infant formula standard. A special note could be added regarding the higher iron requirements for older infants and young children, bearing in mind that the introduction of iron rich complementary foods at the age of six months can also meet these needs. Excess iron intakes from fortified commercial baby foods and milks may increase long-term health and development risks for children.
8. The protection of "consumer" health as a key mandate for Codex should especially apply in the case older infants and young children. Optimal infant and young child feeding practices have life long implications for health and development and therefore need special consideration.
9. The failure of the separate Follow-on Formula standard to protect child health while favouring the marketing and trade needs of the producing countries is illustrated by the aggressive promotion of the Auckland-based Export New Zealand Ltd*, Bibere* brand to Cambodia. Monitoring reports point to the Bibere facebook showing multiple Code violations of parents receiving free Bibere formula products. (Phnom Phenh Post, Oct 22, 2015, *Watchdog calls out firm for marketing formula.*) The Cambodian government banned all such advertisements and promotions of formula milks in 2005 with Sub-Decree 133, which prohibits promotion of products up to the age of 24 months – both directly to the public and specifically throughout the health care system.
10. Overall IBFAN is concerned that the options put forward - and those overlooked - would not ensure the safety, quality, appropriate use and marketing of this product.
11. Breastmilk is environmentally sustainable. Breastfeeding has no negative impact on the environment and the capacity of our planet to allow all people to live well and healthily, now and in the future. In contrast, formula feeding is unsustainable and leaves a large, heavy ecological footprint which includes the resources consumed during the production of the formula as well as the waste left behind. The carbon footprint of greenhouse gases left behind contributes to climate change, while waste and garbage pollute our environment. Among all the categories of formulas, the Follow-up formula which includes so called 'Growing up Milks' and 'Toddler Milks" contributes significantly to the **environmental burden.**
1. IBFAN also wishes to highlight the additional health risks when infants and young children 6 to 24 months are not breastfed. A recent systematic review to determine the impact of optimal breastfeeding practices in children 6–11 and 12–23 months of age found that those who were not breastfed had 1.8- and 2.0-fold higher risk of mortality, respectively, when compared to those who were breastfed. The authors concluded that the risk was twofold higher in nonbreastfed children when compared to breastfed children aged 6–23 months. [2]

Specific Comments

Page 3 - last two lines and top of Page 4:
What evidence is there that *"globally, iron and the quality of dietary fat in the diet were consistently found to be inadequate in sub-groups of the populations. Other nutrients frequently found to be limited in the diets of infants and young children…..*
Does this mean that the FUFs are now being positioned to address nutritional inadequacies or to meet some of the nutritional requirements of young children - the lack of necessity for these products makes it impossible to define what nutrients should be added to the FUF "milk" products when it is intended to be a

[2] http://onlinelibrary.wiley.com/doi/10.1111/apa.13147/abstract

part of a complementary feeding diet which consists of increasing intakes of nutrient and iron rich family foods and a decreased reliance on breastmilk to two years and beyond. With such a variation in complementary feeding across the globe how can a standard address "flexibility" in nutritional needs?

Page 3 - Para 10:
Rephrase to read: Several eWG members did not seem to understand that standards are designed to be read by regulators - not consumers - and can be used in trade disputes. If a revised standard is agreed upon, adding wording that the product is not necessary might assist Member States who wish to adopt strong legislation on these products.

Page 4:
"The majority of eWG members suggested that reference to relevant WHA resolutions be incorporated into the Scope of the Standard, similar to the approach and wording of Section 1.4 of the Standard for Infant Formula. Many of those eWG members who suggested reference to WHA resolutions be contained within the Scope, also suggested that principles contained within the relevant resolutions will also need be considered as part of the review of the labelling provisions for follow-up formula.

Several eWG members commented that the review of the Scope and Labelling requirements did not form part of the ToR for the 2015 eWG and therefore discussions on this issue should be deferred until such time as the group is able to simultaneously review the Scope and Labelling sections of the Standard. The Chairs agree that discussions and a decision about if, and how, applicable WHA resolutions should be incorporated into the Standard for Follow-up Formula fall outside the terms of reference for the eWG, and as such should be deferred until a time when this is specifically addressed. The Chairs would however like to acknowledge the information below provided by eWG members. It is proposed that these valuable comments are noted and considered in future discussions around WHA resolutions."

Clearly the majority of the eWG members have stated that the WHA resolutions regarding the lack of necessity for these products should be in the Scope. Why does this discussion need to be deferred if the majority have made it clear that this is fundamentally important to how the revision evolves? Deferring such a fundamental provision during the process of the revision of the FUF standard may compromise other safeguards necessary to protect young child health from the risks of using industrial milk products and industrially based nutrients as sources of nutrition during the critical stages of health, development and growth.

Page 5 – Description:
Using the wording "from the 6th month on" is ambiguous. It is critical that the products not be used before the age of six months. The term "from the 6th month on" can imply that the product may be used after the 5th month. The wording should read: "from the age of 6 months onward" .

Product that are not necessary should not be targeted consumption by older infants and young children. Nor should they be used until after 12 months as a part of a diversified complementary family food based diet.

Page 6 - 4th - para below the box: Rephrase*: the nutritional safety and adequacy of FUF shall be established by an independent systematic review of all available evidence.*
Page 6 Last para 6.1: There was **NO** general agreement that there should be a point of differentiation at 12 months.
Para 10 - beginning: "*For some nutrients*….Did the majority call for a deviation from the IF standard (other than for iron)?
Page 9 - last Para: The chair's conclusion that trade considerations should take precedence over health concerns regarding the maximum levels of protein is not acceptable. The protection of "consumer" health is a primary mandate for Code. [3]
Page 11 - Box - Footnote 6: Throughout the document all references to evaluation and scrutiny and

[3] *"Some eWG members noted that alignment with the Infant Formula Standard would result in a reduction in protein content in follow-up formula which does not align with the current compositional range for protein in the Standard for Follow-up Formula (current range: 3.0 -5.5 g/100 kcal**). It was noted that this could cause significant issues for trade as current formulations of follow-up formula will not comply with the protein requirements**. Furthermore this will have issues as national jurisdictions begin to adopt the revised Standard for Follow-up Formula. The Committee will need to consider how to accommodate an approach which would result in such a shift in composition, and if this was the preferred approach whether a transition period for implementation would be required. **Due to the lack of strong scientific justification in establishing a maximum limit and potential impact on trade**, it is recommended that a maximum level of 3.5 g/100 kcal is established to enable the transition to lower protein content of follow-up formula globally*

reviews should be stress that such reviews should be independent of those manufacturing and distributing the products in question.

Page 13,14: The addition of **DHA** whether as an optional additive remains controversial as there is no conclusive evidence that the addition confers added benefits. *"LCPUFA supplementation of infant formulas failed to show any signifcant effect on improving early infant cognition. Further research is needed to determine if LCPUFA supplementation of infant formula has benefits for later cognitive development or other measures of neurodevelopment."* [4]

Concluding comments:

1. IBFAN does not agree with the assumption that FUF are a suitable format to provide essential nutrients required for the growth and development of young children. The context in which nutrients are provided is of critical importance during the older infant and early childhood developmental stage. It is a time of exploring the tastes, textures, colours and the aromas of foods. Prolonged feeding of FUF will have a negative effect on the development of taste preferences with life long impact on dietary preferences. Moreover, in addition to the risks of excess nutrient intakes, nutrients provided as additives to industrially produced foods frequently differ in chemical configuration and impact compared to nutrients derived from natural foods and whole milk dairy products. [5]
2. *IBFAN* is of the opinion that there is no necessity for a separate standard for follow on formula and that one renamed *Standard for Formulas for Infants and Young Children* could cover Infant formula and Follow-on formula and be applicable across the whole of the first year of life and beyond . The standard could include a preamble stating that products other than infant formula are not necessary and can be banned from import.
3. IBFAN does not believe there is any need for follow-up formula products (sometimes referred to as 'Toddler' or 'growing up' milks – (a term that is in itself an implied health claim) for children over the age of 1 year, in exceptional circumstances if health professionals believe there is a need for an artificial milk product, infant formula can remain the product of choice. After six months infants and young children need a diversified diet of energy and nutrient rich culturally appropriate, local foods along with breastmilk as the way to achieve the highest attainable level of health, growth and development. The marketing of costly commercial fortified, sweetened and/or flavoured milk products will interfere with the recommended way to feed infants and young children, confuses parents and compromises the health of children by contributing to NCDs and dental disease.
4. The revoking of the Codex standard for follow-up formula has significant potential to protect infant and young child health. Major health bodies have stated that these products are not necessary (WHO, EFSA), hence the removal of this standard will prompt national governments to take effective action to reduce the widespread misleading marketing of FUFs and formulas for older babies.
5. The marketing of FUF misleads parents and encourages them to believe that these products are essential, that the nutrients they provide as 'hard to get' and that they have benefits above and beyond breastfeeding and healthy family foods. Additionally the removal of the standard would facilitate the ability of national governments to restrict these products that interfere with national policies and recommendations for optimal infant and young child feeding. Where there is a need for the use of breastmilk substitutes, infant formula can continue to be used beyond six months and for young children milk of animals (such as cow's milk) can be a part of the complementary food diet. [6]
6. In 2013 the **European Food Safety Authority** concluded that Growing Up Milks have no additional value to a balanced diet. [7]
7. In 2014 **EFSA updated its advice on infant and follow-on formulae**: "*The Panel did not consider it necessary to propose specific compositional criteria for formulae consumed after one year of age, as formulae consumed during the first year of life can continue to be used by young children."* [8]
8. A number of studies from Australia, USA, Canada, and the UK have shown that to circumvent restrictions on the marketing of infant formula for the first six months, the promotions of FUF, toddler

[4] Pediatrics 2012;129:1141–1149

[5] Lawrence M (2013). Food Fortification: The evidence, ethics and politics of adding nutrients to food. Oxford: Oxford University Press.

Jacobs DR, Mursu J, Meyer KA (2012). The importance of food. Archives Pediatrics and Adolescent Medicine; 166; 187-188.

Eichler K, Ruthermann I, Brugger U (2012) Effects of micronutrient fortified milk and cereal food for infants and children: A systematic review. BMC Public Health, 12, 506-519.

Sacco JE, Dodd KW, Kirkpatrick SI,Tarsuk V (2013). Voluntary food fortification in the United States: potential for excessive intakes. European Journal of Clinical Nutrition (6 March 2013) Idoi:10.1038/ejcn.2013.51.

[6] http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf

[7] *'Growing-up' formula: No additional value to a balanced diet, says EFSA* October 2013. http://www.efsa.europa.eu/en/press/news/131025

[8] *EFSA updates advice on infant and follow-on formulae* **24 July 2014** http://www.efsa.europa.eu/en/press/news/140724

"milks", increased, using cross branding to increase the profile of all their age targeted formula products.[9]

9. At national level governments should be encouraged to ensure that any product marketed for children 0 -12 months or 12-36 months do not carry health or nutrition claims, have sugar content restricted, are not flavoured, contain only ingredients that have been pre-authorised for this age group and have specified and appropriate minimum and maximum nutrient values. Any product carrying the same branding as infant formula must be suitable for newborn infants.

10. WHO makes clear in its 2013 statement entitled, *Information concerning the use and marketing of follow-up formula, "… If follow-up formula is marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement for breast milk, it is covered by the Code. In addition, where follow-up formula is otherwise represented in a manner which results in such products being perceived or used as a partial or total replacement for breast milk, such product also falls within the scope of the Code."*[10]

11. As mentioned above, since the current standard for IF is adequate to address the needs for older infants, the labelling can be strengthened to provide better consumer protection. Inadequacies in labelling provisions such as the use of misleading claims regarding the addition of optional ingredients persist, the lack of information for reconstitution of PIF to safeguard against *Cronobacter sakazakii* infections, the lack of information about risks are all areas where labelling can be improved to be in full compliance with both Codex standards and the International Code of Marketing of Breastmilk Substitutes and subsequent relevant WHA resolutions.

[9] Smith J, Blake M. Infant food marketing strategies undermine effective regulation of breast-milk substitutes: trends in print advertising in Australia, 1950-2010. Aust N Z J Public Health. 2013 Aug;37(4):337-44.
Berry NJ, Jones SC, Iverson D. Circumventing the WHO Code? An observational study. Arch Dis Child. 2012 Apr;97(4):320-5.
Berry NJ, Jones SC, Iverson D. Relax, you're soaking in it: sources of information about infant formula. Breastfeed Rev. 2011 Mar;19(1):9-18.
Berry NJ, Jones S, Iverson D. It's all formula to me: women's understandings of toddler milk ads. Breastfeed Rev. 2010 Mar;18(1):21-30.

[10] http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf