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 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 4 **NFSDU/39 CRD/07**

Original language only

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

Thirty-ninth Session

Berlin, Germany
4 - 8 December 2017

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

Comments of Costa Rica, El Salvador, European Union, Kyrgyzstan, Morocco, Nigeria, Sierra Leone, Sri Lanka, African Union and EU Specialty Food Ingredients

COSTA RICA

Costa Rica agradece a Nueva Zelanda, Francia e Indonesia por el trabajo realizado en la coordinación del grupo electrónico, así como en la preparación del documento CX/NFSDU 17/39/4, REVISIÓN DE LA NORMA PARA PREPARADOS COMPLEMENTARIOS (CODEX STAN 156-1987). Además agradece nuevamente la oportunidad de presentar comentarios específicos sobre este tema según se detalla para cada una de las recomendaciones.

Recomendación 1:

Que el CCNFSDU acuerde revisar los requisitos relativos a las proteínas del siguiente modo:

1. Que se establezca un contenido mínimo de proteínas de 1,6 g/100 kcal y que se precise una evaluación clínica para los preparados con unos contenidos de proteínas lácteas no hidrolizadas inferiores a 1,8 g/100 kcal.

Tomando en consideración la conclusión de la EFSA (2017): "... El Panel concluye que el uso de FUF con un contenido proteico de al menos 1,6 g / 100 kcal de proteína de leche de vaca intacta o proteína de leche de cabra intacta que de otra manera cumpla con los requisitos de la legislación pertinente de la UE es seguro y adecuado para los bebés que viven en Europa con acceso a alimentos complementarios de calidad suficiente ... " Costa Rica sugiere acordar un mínimo de 1.8 g de proteína por 100 kcal para la fórmula para lactantes mayores, ya que no se puede asegurar que en los países en desarrollo se alcancen ingestas dietéticas comparables con las europeas. La EFSA indica que solo en esos casos es que podrían aplicarse las conclusiones del panel. También apoya la armonización, por lo que recomienda dejar un valor único de 1,8 g / 100 kcal para la proteína en lugar de dejar abierta la posibilidad de realizar evaluaciones clínicas para los preparados con un contenido de proteínas lácteas no hidrolizadas inferiores a 1,8 g/100 kcal.

Referencia: EFSA (2017) Proyecto de dictamen científico sobre la seguridad e idoneidad para el uso por parte de los lactantes de preparados de continuación con un contenido de proteínas de al menos 1,6 g / 100 kcal.

2. Que se conserve el valor mínimo de proteínas para los aislados de proteínas de soja y que se enmiende la segunda oración de la nota 5 a pie de página para que siga la línea de la primera (mediante la inclusión de «ni de la leche de cabra»).

Costa Rica apoya el mantenimiento de 2.25 g / 100 kcal como mínimo para las fórmulas basadas en aislado de proteína de soja, ya que no hay evidencia por el momento para modificar este valor.

3. Que se conserve el contenido mínimo actual para los preparados complementarios a base de proteínas hidrolizadas.

Costa Rica apoya el mantenimiento de 2.25 g / 100 kcal como mínimo para las fórmulas basadas en proteína hidrolizada, ya que no hay evidencia por el momento para modificar este valor.

4. Que se combinen las dos oraciones de la nota 6 a pie de página relativas a la evaluación clínica de los preparados a base de proteínas de la leche no hidrolizadas que contengan menos de 1,8 g de

proteínas/100 kcal y los preparados a base de proteínas hidrolizadas que contengan menos de 2,25 g de proteínas/100 kcal.

Costa Rica apoya esta recomendación, dado que considera que son las fórmulas con menos de 1,8 g de proteína/100 kcal, así como las que contengan menos de 2,25 g de proteína hidrolizada/100 kcal, las que deben evaluarse. Asimismo, en caso de modificación la redacción de la segunda parte de la nota al pie, Costa Rica apoya siempre que quede claro que la evaluación es basada en estudios clínicos y la realiza la autoridad competente a nivel nacional o regional.

Se proponen las siguientes enmiendas al texto:

a) Proteínas 2), 3), 4)

Unidad	Mínimo	Máximo	NSR
g/100 kcal	~~[1,6]~~ 1.8 5), 6)	3	-
g/100 kJ	~~[0,38]~~ 0.43 5), 6)	0,72	-

2) Para los fines de la presente Norma, el cálculo del contenido de proteínas del producto final listo para el consumo deberá basarse en N x 6,25, salvo que se proporcione una justificación científica para el uso de un factor de conversión diferente aplicable a un determinado producto. Los niveles establecidos para las proteínas en esta Norma se basan en el factor de conversión de nitrógeno de 6,25. A efectos informativos, el valor de 6,38 se usa como factor específico apropiado para la conversión del nitrógeno en proteínas en otras normas del Codex para productos lácteos.

3) Para un valor energético equivalente, el preparado debe contener una cantidad disponible de cada aminoácido esencial y semiesencial igual al menos a la que contiene la proteína de referencia (leche materna, según se define en el anexo I de la *Norma para preparados para lactantes y preparados para usos medicinales especiales destinados a los lactantes* [CODEX STAN 72-1981]); no obstante, a efectos de cálculo, las concentraciones de tirosina y fenilalanina y las concentraciones de metionina y cisteína pueden sumarse.

4) Podrán añadirse al preparado complementario aminoácidos aislados únicamente a fin de mejorar su valor nutritivo para los lactantes. Para mejorar la calidad de las proteínas, podrán añadirse aminoácidos esenciales y semiesenciales, pero solo en las cantidades necesarias a tal efecto. Tan solo podrán utilizarse las formas L de los aminoácidos.

5) El valor mínimo se aplica a las proteínas de la leche de vaca y de cabra. En los preparados complementarios a base de proteínas lácteas no provenientes de la leche de vaca **[ni de la leche de cabra]** tal vez sea necesario aplicar otros valores mínimos. En los preparados complementarios a base de aislados de proteínas de soja se aplica un valor mínimo de **[**2,25 g/100 kcal (0,5**4** g/100 kJ)**]**.

~~[6) Los preparados complementarios a base de proteínas de la leche no hidrolizadas que contengan [1,61-1,8 g] de proteínas/100 kcal deberán ser evaluados clínicamente por una autoridad nacional o regional competente. Los preparados complementarios a base de proteínas hidrolizadas que contengan menos de [2,25 g de proteínas/100 kcal] deberán evaluarse clínicamente.~~

[6) Los preparados complementarios a base de proteínas de la leche no hidrolizadas que contengan **[menos de 1,8 g]** de proteínas/100 kcal **[(0,43 g/100 kJ)]** y los preparados complementarios a base de proteínas hidrolizadas que contengan menos de [2,25 g de proteínas/100 kcal] **(0,54 g/100 kJ)** deberán ser evaluados clínicamente por una autoridad nacional o regional competente.

Recomendación 2:

Que el CCNFSDU acuerde lo siguiente:

Que en la nota al pie sobre la adición opcional de ácido docosahexaenoico se establezca un nivel mínimo de 13 mg/100 kcal (3,1 mg/100 kJ).

Costa Rica aún no define una posición para esta recomendación.

Que el NSR acordado del 0,5 % del contenido total de ácidos grasos se convierta en 30 mg/100 kcal (7,9 mg/100 kJ).

Con respecto al NSR, Costa Rica en el GTE también apoyó el punto medio del rango de grasa definido para estos productos, es decir 26 mg / 100 kcal. Sin embargo, si la mayoría de miembros se inclina por el valor recomendado de 30 mg/100 kcal, no tiene objeción.

Con respecto a las posibles desviaciones nacionales/regionales, Costa Rica considera que una norma del Codex debería limitar estas desviaciones para que sean eficientes. Sin embargo, entiende que, en algunas regiones, el consumo de pescado es mayor debido a razones culturales y geográficas y, por lo tanto, la ingesta de DHA a partir de alimentos complementarios puede ser mayor que en otras partes del mundo. Por lo anterior, se propone modificar ligeramente la última oración del párrafo del DHA para que sea más legible: "según corresponda, para abordar las necesidades nutricionales de su correspondiente población local".

En consecuencia, Costa Rica sugiere las siguientes enmiendas al texto:

Ácido docosahexaenoico [20)]			
Unidad	**Mínimo**	**Máximo**	**NSR**
mg/100 kcal	[20)]	-	**~~[~~30~~]~~ o 26**
mg/100 kJ	[20)]	-	**~~[~~7,9~~]~~ o 6.2**
20) Si se añade ácido docosahexaenoico (22:6 n-3) a los preparados complementarios, deberá alcanzarse un nivel mínimo de [**13 mg/100 kcal (3,1 mg/100 kJ)**] y el contenido de ácido araquidónico (20:4 n-6) deberá alcanzar por lo menos la misma concentración que el ácido docosahexaenoico. El contenido de ácido eicosapentaenoico (20:5 n-3), que puede encontrarse en fuentes de AGPI-CL n-3, agregado como fuente de DHA no debería superar el contenido de ácido docosahexaenoico. Las autoridades nacionales o regionales competentes podrán apartarse de las condiciones anteriores, según convenga **para abordar** ~~en función de~~ las necesidades nutricionales de su correspondiente población local.			

Table 7: Conversion of percentage fatty acid requirements to absolute DHA requirements

Fat composition of follow-up formula for older infants	**DHA level**	
	0.3% of total fatty acids	0.5% of total fatty acids
Minimum fat: 4.4 g/100 kcal	13 mg/100 kcal 3.1 mg/100 kJ	22 mg/100 kcal 5.3 mg/100 kJ
Maximum fat: 6.0 g/100 kcal	18 mg/100 kcal 4.3 mg/100 kJ	33 mg/100 kcal 7.9 mg/100 kJ
Mid-point of the range: 5.2 g/100 kcal	16 mg/100 kcal 3.8 mg/100 kJ	26 mg/100 kcal 6.2 mg/100 kJ

Información para referencia:

(1) These are the minimum & maximum values agreed for fat in follow-up formula for older infants.

Recomendación 3:

Que el CCNFSDU acuerde establecer un nivel mínimo para la grasa de 3,5 g/100 kcal (0,84 g/100 kJ).

Costa Rica apoya la propuesta de tener un mínimo de 3.5 g de grasa por cada 100 kcal. Esta cantidad es la mínima que respaldaría un consumo adecuado de grasa en el grupo de edad objetivo.

Esta cantidad representa el 31.5% de la energía del producto, en línea con la recomendación del Instituto de Medicina que indica que la grasa en la dieta de los niños de 1 a 3 años debería proporcionar entre 30-40% de la energía como grasa.

Es transcendental tener en cuenta la importancia de mantener un perfil lipídico adecuado para el producto.

Referencia: Institute of Medicine (2001) Ingestas dietéticas de referencia para energía, carbohidratos, fibra, grasa, ácidos grasos, colesterol, proteínas y aminoácidos. The National Academies Press, Washington DC.

Recomendación 4:

Que el CCNFSDU acuerde establecer un nivel máximo de 12,5 g/100 kcal (3 g/100 kJ) para los carbohidratos disponibles.

Costa Rica considera que un máximo de 14 g de carbohidratos / 100 kcal, permitiría un equilibrio adecuado de macronutrientes en el producto. Además, este valor se alinea con la recomendación hecha por la Early Nutrition Academy (Suthutvoravut, 2015) para estos productos, así como con el máximo permitido en la CODEX STAN 72 para Preparados para Lactantes.

Recomendación 5:

Se recomienda que el CCNFSDU:

1. acuerde establecer un límite del 20 % de los carbohidratos disponibles para los monosacáridos y los disacáridos distintos de la lactosa;

Costa Rica apoya un máximo para el azúcar agregado, distinto a la lactosa como el 20% de los carbohidratos disponibles, que es equivalente a aproximadamente al 10% de la energía como límite máximo, en línea con la recomendación formulada por la OMS en 2015.

Referencia: OMS (2015) Pauta: Ingesta de azúcares para adultos y niños. Ginebra: Organización Mundial de la Salud.

2. acuerde restringir los carbohidratos con sabor dulce, de conformidad con la nota 4 a pie de página enmendada que se incluye más abajo; y

Costa Rica apoya esta recomendación. Sin embargo, en el pie de página, la oración “sacarosa y/o fructosa no deben ser agregadas a menos que sean necesarias como fuentes de carbohidratos”, la frase “a menos que sean necesarios como fuente de carbohidratos” está sujeta a interpretación y es redundante ya que la adición de fructosa y sacarosa está restringida por el límite que se establezca para mono y disacáridos.

En la norma del Codex para fórmulas infantiles se establece que tanto la sacarosa como la fructosa como ingredientes deben evitarse en fórmulas infantiles por los síntomas que amenazan la vida de los niños pequeños con intolerancia hereditaria no reconocida a la fructosa. Sin embargo, una vez los niños inician la alimentación complementaria no hay razón para continuar con esta restricción. EFSA (EFSA, 2014) comenta lo siguiente: debido a que la alimentación complementaria proveerá otros carbohidratos distintos a la lactosa no existe una razón para restringir el uso de sacarosa y fructosa en fórmulas de seguimiento siempre y cuando no se exceda un nivel máximo.

Costa Rica considera innecesario mencionar ingredientes que aportan mono y disacáridos, pues ya éstos quedarían limitados con el valor máximo que se acuerde para éstos.

3. examine la necesidad de limitar la adición de ingredientes distintos de los carbohidratos que se agreguen con fines edulcorantes.

Costa Rica considera que la frase "otros carbohidratos que contribuyen al sabor dulce" es poco clara. La dulzura se puede definir en relación con la sacarosa (ESPGHAN, 2017), pero el sabor dulce está influenciado por diferentes factores (por ejemplo, genotipo o edad) (ESPGHAN 2017, Mennella et al 2016) y también la matriz alimentaria.

Asimismo, el uso de ingredientes diferentes a los carbohidratados que contribuyen al sabor dulce ya está controlado por la ausencia de permisos para ser agregados como Aditivos Alimentarios en el Codex STAN 192-1995, por lo que no es necesario incluir ningún texto al respecto.

En consecuencia se sugieren las siguientes modificaciones al texto:

Carbohidratos **Carbohidratos disponibles [4)]**			
Unidad	**Mínimo**	**Máximo**	**NSR**
g/100 kcal	-	~~[12,5]~~ **[14]**	-
g/100 kJ	-	~~[3,0]~~	-

4) La lactosa deberá ser el carbohidrato preferido en [nombre del producto] a base de proteínas de la leche. ~~Los azúcares distintos de la lactosa [u otros carbohidratos que contribuyan al sabor dulce de [nombre del producto]] no deberán superar el [10 %] o el [20 %] de los carbohidratos disponibles. No deberán añadirse sacarosa ni fructosa, a menos que sean necesarias como fuentes de carbohidratos.~~

~~[~~Los monosacáridos y los disacáridos~~]~~ distintos de la lactosa no deberán superar el 20 % de los carbohidratos disponibles. ~~**[Los monosacáridos y los disacáridos incluyen los azúcares naturalmente presentes en la miel, los jarabes, los jugos de frutas y los concentrados de jugos de frutas.]** No deberán añadirse sacarosa ni fructosa **[ni otros carbohidratos que contribuyan al sabor dulce de [nombre del producto]]**, a menos que sean necesarias como fuentes de carbohidratos. **[No deberán añadirse otros ingredientes distintos de los carbohidratos].**~~

Recomendación 6:

Que el CCNFSDU acuerde convertir el límite porcentual para los azúcares [y otros carbohidratos que contribuyan al sabor dulce] en una cantidad absoluta basada en el contenido energético del producto para niños pequeños (g/100 kcal y g/100 kJ) una vez que se tome una decisión sobre el nivel máximo de carbohidratos disponibles.

Costa Rica apoya esta recomendación, con la eliminación del texto [y otros carbohidratos que contribuyan al sabor dulce] según lo que señaló al respecto para la recomendación 5.

Recomendación 7:

Que el CCNFSDU acuerde no incluir ninguna proporción de calcio/fósforo para [nombre del producto] para niños pequeños.

Costa Rica considera que se debe mantener una proporción calcio/fósforo de un mínimo de 1: 1 y un máximo de 2: 1, ya que esta relación es relevante para la mineralización ósea, muy importante para los niños en crecimiento (1-3 años).

Recomendación 8:

Que el CCNFSDU acuerde la adición obligatoria de vitamina D y los niveles mínimo y máximo que se exponen a continuación:

Vitamina D			
Unidad	**Mínimo**	**Máximo**	**NSR**
µg9)/100 kcal	[1,5]	[4,5]	-
µg9)/100 kJ	[0,36]	[1,08]	-
9) Calciferol. 1 µg de calciferol = 40 UI de vitamina D.			

Costa Rica apoya esta recomendación.

Recomendación 9:

1) Que el CCNFSDU acepte el enfoque propuesto por la Secretaría del Codex y la OMS consistente en incluir un preámbulo en la *Norma para preparados complementarios* que contenga una referencia concreta a los documentos de la OMS y las resoluciones de la AMS pertinentes, teniendo en cuenta que este enfoque sobre el preámbulo sustituiría la necesidad de incluir una lista o referencias de estos documentos y estas resoluciones en las distintas secciones de la *Norma*.

Costa Rica apoya el enfoque propuesto por la Secretaría del Codex y la OMS para el preámbulo, pues consideramos que es preferible no incluir una lista o referencias de los documentos de la OMS y las resoluciones de la AMS pertinentes, pero sí una referencia concreta a los mismos.

2) Que el CCNFSDU acuerde el siguiente texto para el preámbulo, tal como lo han propuesto la Secretaría del Codex y la OMS, y que seleccione la expresión que prefiera de entre las presentadas entre corchetes:

Costa Rica apoya el texto con algunas modificaciones, la más relevante consiste en eliminar la frase “Las directrices y las políticas pertinentes de la OMS y las resoluciones pertinentes de la Asamblea Mundial de la

Salud (AMS) que hayan recibido [la aprobación/el respaldo] de los Estados miembros [también pueden servir/sirven] de orientación a los distintos países en este contexto.", esto por cuanto el tema de las políticas de la OMS y el mandato del Codex se revisarán en la Comisión del Codex Alimentarius CAC 41 el próximo año.

Si el Comité mantiene la frase, su redacción debería limitarse a: "Las directrices y políticas pertinentes de la OMS, así como las resoluciones pertinentes de la Asamblea de la Asamblea Mundial de la Salud que han sido respaldadas por los Estados miembros también pueden proporcionar orientación a los países en este contexto."

Se proponen en consecuencia las siguientes enmiendas:

La Comisión del Codex Alimentarius confirma la necesidad de ~~[~~proteger **y apoyar** ~~y respaldar/reconocer]~~ la lactancia **materna** como un medio incomparable para proporcionar un alimento ideal para el crecimiento y el desarrollo saludables de los lactantes. Al mismo tiempo, el Codex reconoce que numerosos preparados se han elaborado o destinado al uso, cuando fuera ~~[~~necesario~~/pertinente]~~, como sucedáneos de la leche materna para cubrir las necesidades nutricionales normales de los lactantes, siempre que se preparen en condiciones higiénicas y se suministren en las cantidades adecuadas. También se han elaborado varios productos específicamente destinados a los niños pequeños que son adecuados para su transición a un régimen alimentario más diversificado basado en alimentos preparados en el hogar, ~~y~~ dado que estos productos no se han formulado ni intentan ser sucedáneos de la leche materna no deben desalentar la práctica de la lactancia natural.

La elaboración, la distribución, la venta y el uso de preparados complementarios para lactantes de más edad y [nombre del producto] para niños pequeños deben seguir las políticas nacionales sobre salud y nutrición y la normativa nacional o regional pertinente, además de tener en cuenta, ~~[cuando proceda,]~~ las recomendaciones realizadas en el Código internacional de comercialización de sucedáneos de la leche materna (1981) y la Estrategia mundial para la alimentación del lactante y del niño pequeño. ~~Las directrices y las políticas pertinentes de la OMS y las resoluciones pertinentes de la Asamblea Mundial de la Salud (AMS) que hayan recibido [la aprobación/el respaldo] de los Estados miembros [también pueden servir/sirven] de orientación a los distintos países en este contexto.~~

La presente Norma está dividida en dos secciones. La sección A se refiere a los preparados complementarios para lactantes de más edad (6 a 12 meses) y la sección B trata de [nombre del producto] para niños pequeños (12 a 36 meses). No se aplica a los productos regulados por la Norma del Codex para preparados para lactantes (CODEX STAN 72-1981).

Recomendación 10:

Que el CCNFSDU adopte el siguiente texto para el punto 1.1:

1.1 Esta sección de la Norma se aplica a los preparados complementarios para lactantes de más edad definidos en la sección 2.1, en forma líquida o en polvo.

Costa Rica apoya la recomendación 10.

Recomendación 11:

Que el CCNFSDU adopte el siguiente texto para el punto 1.2:

Costa Rica apoyó en el GTE una redacción menos específica para la sección 1.2, entendemos que hay más aspectos cubiertos por la norma, pero también consideramos que esos aspectos son requisitos de composición, calidad o seguridad, por lo que no consideramos necesario nombrarlos todos. Sin embargo, no nos oponemos a las enmiendas propuestas entre corchetes, a excepción de los requisitos analíticos, dado que éstos están relacionados con la composición, la calidad y la inocuidad, por lo que no es necesario incluirlos en esta descripción general. Además, los requisitos analíticos no se mencionan en el alcance de la Norma del Codex para preparados para lactantes (CODEX STAN 72 - 1981). Por tanto la sección 1.2 se leería como sigue:

1.2 Esta sección de la Norma contiene los requisitos de composición, calidad, inocuidad, y ~~[~~etiquetado ~~y análisis]~~ relativos a los preparados complementarios para los lactantes de más edad.

Recomendación 12:

Que el CCNFSDU adopte el siguiente texto para el punto 1.3 y seleccione la expresión que prefiera («deberán presentarse» o «se presentarán»):

Costa Rica apoya la recomendación 12 en línea con la conclusión de la presidencia del GTE, Costa Rica apoya esta recomendación y favorece la palabra "deberá" en lugar de "debería" ya que esto es más

consistente con la terminología utilizada en la sección de etiquetado de la Norma, el texto quedaría como sigue:

1.3 Solo [deberán presentarse~~/se presentarán~~] como~~]~~ preparados complementarios para lactantes de más edad los productos que cumplan con los criterios establecidos en las disposiciones de esta sección de la presente Norma.

Recomendación 13:

Que el CCNFSDU acuerde lo siguiente:

Incluir una referencia a los documentos de la OMS y las resoluciones de la AMS en el preámbulo en lugar de en el ámbito de aplicación y que esta referencia siga la recomendación de la Secretaría del Codex y la OMS presentada en la sección 5.3 de este documento

Eliminar la disposición 1.4 relativa a los preparados complementarios para lactantes de más edad del ámbito de aplicación, ya que, con el enfoque propuesto consistente en incluir una referencia a los documentos de la OMS y las resoluciones de la AMS en el preámbulo, esta disposición del ámbito de aplicación sería redundante.

Costa Rica no está de acuerdo con la primera parte de la recomendación 13 y se refiere a sus comentarios con respecto a la Recomendación 9 anterior. Creemos que es prematuro agregar la oración "Directrices y políticas pertinentes de la OMS, así como resoluciones relevantes de la Asamblea Mundial de la Salud (AMS) que han sido [respaldadas / apoyadas] por los Estados miembros [también pueden] brindar orientación a los países en este contexto".

El tema más amplio de las políticas de la OMS y el mandato del Codex será considerado en la próxima sesión de la Comisión del Codex Alimentarius (CAC41) para permitir una discusión informada y decisiones, por lo tanto, Costa Rica sugiere la eliminación de la oración en esta Norma del Codex.

Recomendación 14:

Que el CCNFSDU apruebe el siguiente párrafo introductorio para la sección de etiquetado aplicable a los preparados complementarios para lactantes de más edad (sección A):

Costa Rica aún no define una posición para esta recomendación.

Recomendación 15:

Por ahora, no es preciso adoptar ninguna decisión sobre la necesidad de revisar las declaraciones de propiedades nutricionales una vez que se finalicen los VRN para los lactantes y los niños pequeños.

Se recomienda que el CCNFSDU convenga que no debe retrasarse el proceso de revisión de esta Norma y que toda consideración sobre los VRN (si se establecen para este grupo de edad) y la finalidad de dichos VRN en las Directrices sobre etiquetado nutricional (CAC/GL 2-1985), incluida la necesidad de determinar si deberán revisarse las disposiciones relativas al etiquetado de las normas del Codex sobre alimentos para lactantes y niños pequeños en caso de que el Codex adopte VRN, deberá formar parte del mandato de un grupo de trabajo sobre los VRN.

Habida cuenta de que el Comité no puede prever el resultado de ningún posible trabajo sobre los VRN para este grupo de edad, se recomienda mantener el statu quo para las declaraciones de propiedades nutricionales (y saludables): conservar la prohibición de realizar declaraciones de propiedades nutricionales y saludables en los alimentos para lactantes y niños pequeños excepto en los casos específicamente previstos en las normas pertinentes del Codex o en la legislación nacional.

Costa Rica aún no define una posición para esta recomendación.

Recomendación 16:

Que el CCNFSDU adopte el siguiente texto para la sección 9.1 sobre el nombre del producto e indique qué opción prefiere para la disposición 9.1.4, incluyendo el texto entre corchetes.

Costa Rica apoya la recomendación 16 para los puntos 9.1.1 y 9.1.3.

En 9.1.2, Costa Rica no considera necesaria la adición de la palabra "o regional", pero no se opone a ella.

Para la sección 9.1.4 Costa Rica apoya la Opción 1 ya que aporta claridad.

En la Sección 9.1.5, Costa Rica apoya el uso del término "puede"

El texto de leería como sigue:

9.1 Nombre del producto

9.1.1 El texto de la etiqueta y toda otra información que acompañe el producto deberán estar escritos en el idioma o los idiomas apropiados.

9.1.2 El producto se denominará «preparado complementario para lactantes de más edad», tal como se define en la sección 2.1, o cualquier otra denominación apropiada que indique la verdadera naturaleza del producto, de conformidad con las costumbres del país [o de la región].

9.1.3 En la etiqueta se indicará claramente el origen de las proteínas que contiene el producto.

~~9.1.4 OPCIÓN 1: Dividir la disposición 9.1.4 en dos:~~

9.1.4(a) Si el origen de las proteínas[*] es exclusivamente la leche ~~[~~de nombre del animal~~]~~, el producto podrá etiquetarse «preparado complementario para lactantes de más edad a base de ~~[~~proteína de~~]~~ leche ~~[~~de nombre del animal~~]~~».

9.1.4(b) Si el origen de las proteínas[*] es exclusivamente ~~[~~nombre del vegetal~~]~~, el producto podrá etiquetarse «preparado complementario para lactantes de más edad a base de ~~[~~proteína de~~]~~ ~~[~~nombre del vegetal~~]~~».

~~[~~* Se aclara que la adición de distintos aminoácidos, cuando sean necesarios para mejorar la calidad de las proteínas, no impide el uso de las opciones de etiquetado anteriores.~~]~~

~~O bien~~

~~OPCIÓN 2: Eliminar la disposición 9.1.4 por estar cubierta por la disposición 9.1.3.~~

9.1.5 Todo producto que no contenga leche ni ningún derivado lácteo ~~[deberá]~~ [podrá] ~~e~~tiquetarse con la expresión «no contiene leche ni productos lácteos», o una frase equivalente.

Recomendación 17:

Que el CCNFSDU adopte el siguiente texto para la sección 9.2 sobre la lista de ingredientes:

9.2 Lista de ingredientes

9.2.1 En la etiqueta figurará la lista completa de los ingredientes, ~~[incluidos los ingredientes facultativos,]~~ por orden decreciente de proporciones, salvo que, cuando se hayan añadido vitaminas o minerales, estos ingredientes se podrán indicar como grupos separados de vitaminas o de minerales. Dentro de tales grupos no será necesario indicar las vitaminas y los minerales por orden decreciente de proporciones.

9.2.2 Se indicará en la etiqueta el nombre específico de los ingredientes de origen animal o vegetal y de los aditivos alimentarios. ~~[~~Además, para los aditivos alimentarios, podrá indicarse opcionalmente el número del SIN.~~]~~

Costa Rica apoya la recomendación 17.

Recomendación 18:

Que el CCNFSDU adopte el siguiente proyecto de texto para la sección 9.3 sobre la declaración del valor nutritivo:

Costa Rica apoya la recomendación 18, con las siguientes modificaciones:

9.3 Declaración del valor nutritivo

La declaración de información nutricional [de los preparados complementarios para lactantes de más edad] deberá contener las siguientes informaciones, en el orden en que aquí se indican:

a) la cantidad de energía, expresada en kilocalorías (kcal) y/o kilojulios (kJ), y la cantidad en gramos de proteínas, carbohidratos y grasa por cada 100 g o cada 100 ml de alimento vendido, ~~[~~así como~~]~~ ~~[o]~~ por 100 ml del alimento listo para el consumo que se haya preparado de acuerdo con las condiciones indicadas en la etiqueta;

b) la cantidad total de cada vitamina y mineral indicados en el apartado 3.1.3 de la sección A, y de cualquier otro ingrediente indicado en la lista del apartado 3.2 de la sección A, por 100 g o cada 100 ml de alimento vendido, ~~[~~así como~~]~~ ~~[o]~~ por 100 ml del alimento listo para el consumo que se haya preparado según las instrucciones indicadas en la etiqueta;

c) además, se permitirá la declaración del contenido de nutrientes por cada 100 kcal (o por 100 kJ).

Recomendación 19:

Puesto que este documento se ha redactado antes de la celebración de la 44.ª reunión del CCFL, se recomienda que el CCNFSDU acuerde modificar el texto anterior (según sea necesario) y adopte los cambios propuestos en la citada reunión del CCFL para que su redacción sea coherente con el texto y los resultados de los debates de la reunión del CCFL de octubre de 2017.

Costa Rica apoya la recomendación 19.

Recomendación 20:

Que el CCNFSDU adopte el siguiente texto para la sección 9.5 y examine la redacción modificada propuesta para la disposición 9.5.1:

Costa Rica apoya la recomendación 20, sin embargo en la sección 9.5.6, apoya la inclusión de la frase "no debe usarse como única fuente de nutrición". Si bien las últimas dos oraciones de la sección 9.5.6 tienen un significado similar y pueden considerarse redundantes, la frase que sugerimos mantener garantiza que este producto se diferencie claramente de la fórmula infantil. Asimismo, esto evitaría la confusión con otros productos.

Sugerimos que la sección se lea:

9.5 Instrucciones de uso

9.5.1 Los productos ~~[~~listos para el consumo~~]~~ en forma líquida podrán utilizarse directamente o, en el caso de productos líquidos concentrados ~~[~~y productos en polvo~~]~~, deberán prepararse con agua inocua o agua que se ha vuelto inocua hirviéndola antes de suministrarlos de acuerdo con las instrucciones de uso~~. [Los productos en polvo deberían reconstituirse con agua inocua o agua que se ha vuelto inocua hirviéndola antes de la preparación.]~~ Se darán instrucciones adecuadas para la preparación y manipulación apropiadas de conformidad con las buenas prácticas de higiene.

9.5.2 En la etiqueta se darán instrucciones adecuadas para la preparación y el uso apropiados del producto, así como para su conservación y su eliminación después de su preparación, es decir que deberá desecharse el ~~[~~producto~~]~~ sobrante.

9.5.3 La etiqueta deberá contener instrucciones gráficas claras que ilustren el método de preparación del producto.

9.5.4 Las instrucciones deberían incluir una advertencia acerca de los peligros para la salud que pueden derivarse de un almacenamiento, una preparación o un uso inadecuados.

9.5.5 En la etiqueta se darán instrucciones adecuadas sobre la conservación del producto después de que se haya abierto el envase.

~~[~~9.5.6 La etiqueta de los preparados complementarios para lactantes de más edad deberá contener una declaración de que el producto no se introducirá antes del sexto mes de vida, ~~[de~~ que el producto no deberá usarse como única fuente de nutrientes~~]~~ y de que los lactantes de más edad deberán recibir alimentos complementarios además del producto.~~]~~

Recomendación 21: Que el CCNFSDU adopte el siguiente texto para la sección 9.6 y que examine el texto presentado entre corchetes en las distintas disposiciones.

Costa Rica apoya la recomendación 21 y el texto de la sección 9.6 con algunos ajustes, como sigue:

9.6 Requisitos de etiquetado adicionales

9.6.1 Las etiquetas no deberán desalentar la práctica de la lactancia materna. La etiqueta de cada envase deberá contener un mensaje claro, visible y fácilmente legible que incluya los elementos siguientes:

~~[~~a) Las palabras «aviso importante» o una expresión equivalente~~]~~

b) La declaración «la leche materna es el mejor alimento para su niño» o una declaración similar que indique la superioridad de la lactancia materna o la leche materna

~~[~~c) Una declaración de que el producto deberá utilizarse solamente conforme al asesoramiento proporcionado por un trabajador sanitario independiente acerca de la necesidad de su uso y del método de uso apropiado~~]~~

~~[d) La declaración «el uso de este producto no deberá reemplazar la leche materna ni conducir a la interrupción de la lactancia materna continuada»]~~

~~[~~9.6.2 La etiqueta no deberá contener imágenes de lactantes ~~o mujeres~~ ni ninguna otra imagen~~[,] o texto que idealice el uso de preparados complementarios. La etiqueta no deberá contener fotografías, imágenes, textos ni declaraciones~~ o declaración que pueda:

9.6.2.1 idealizar el uso de los preparados complementarios para lactantes de más edad;

9.6.2.2 sugerir el consumo del producto por lactantes menores de seis meses de edad ~~(incluidas las referencias a hitos y fases)~~;

9.6.2.3 recomendar o promover la alimentación con biberón;

9.6.2.4 afectar negativamente a la práctica de la lactancia materna ~~o desalentar dicha práctica, establecer una comparación con la leche materna,~~ o sugerir que el producto es ~~prácticamente~~ equivalente o superior a la leche materna;

~~9.6.2.5 contener la aprobación de un profesional u organismo o algo que pueda interpretarse como tal, a menos que esto haya sido autorizado específicamente por los organismos reguladores nacionales, regionales o internacionales pertinentes.]~~

9.6.3 No se utilizarán términos como «humanizado», «maternalizado» u otros términos análogos. ~~[~~Además, el producto no deberá compararse con la leche materna.~~]~~

~~[~~9.6.4~~]~~ ~~Los~~ productos serán etiquetados evitando cualquier riesgo de confusión entre preparados para lactantes, preparados complementarios para lactantes de más edad, [nombre del producto] para niños pequeños y preparados para usos medicinales especiales [, y de manera que los consumidores los distingan claramente~~, en particular por el texto, las imágenes y los colores utilizados].~~

Lo anterior según el enfoque adoptado por el GTE en cuanto a que cualquier requisito de etiquetado adicional para la fórmula de seguimiento para lactantes de más edad no debería ser más estricto que lo que se exige en la etiqueta de la fórmula para lactantes.

R**ecomendación 22: Que el CCNFSDU adopte el siguiente texto para el punto 1.1:**

1.1 Esta sección de la Norma se aplica a [nombre del producto] para niños pequeños definidos en la sección 2.1, en forma líquida o en polvo.

Costa Rica apoya la recomendación 22.

Recomendación 23: Que el CCNFSDU adopte el siguiente texto para el punto 1.2:

Costa Rica apoyó en el GTE una redacción menos específica para la sección 1.2, entendemos que hay más aspectos cubiertos por la norma, pero también consideramos que esos aspectos son requisitos de composición, calidad o seguridad, por lo que no consideramos necesario nombrarlos todos. Sin embargo, no nos oponemos a las enmiendas propuestas entre corchetes, a excepción de los requisitos analíticos, dado que éstos están relacionados con la composición, la calidad y la inocuidad, por lo que no es necesario incluirlos en esta descripción general. Además, los requisitos analíticos no se mencionan en el alcance de la Norma del Codex para preparados para lactantes (CODEX STAN 72 - 1981). Por tanto la sección 1.2 se leería como sigue:

1.2 Esta sección de la Norma contiene los requisitos de composición, calidad, inocuidad y~~, [~~etiquetado ~~y análisis]~~ relativos a [nombre del producto] para niños pequeños.

Recomendación 24: Que el CCNFSDU adopte el siguiente texto para el punto 1.3 y seleccione la expresión que prefiera («deberán presentarse» o «se presentarán»):

Costa Rica apoya la recomendación 24 como sigue:

1.3 Solo ~~[~~deberán presentarse~~/se presentarán]~~ como ~~]~~ [nombre del producto] para niños pequeños los productos que cumplan con los criterios establecidos en las disposiciones de esta sección de la presente Norma.

Costa Rica apoya esta recomendación y favorece la palabra "deberá" en lugar de "debería" ya que esto es más consistente con la terminología utilizada en la sección de etiquetado de la Norma.

Recomendación 25: Que el CCNFSDU acuerde lo siguiente:

Incluir una referencia a los documentos de la OMS y las resoluciones de la AMS en el preámbulo en lugar de en el ámbito de aplicación y que esta referencia siga la recomendación de la Secretaría del Codex y la OMS presentada en la sección 5.3 de este documento

Eliminar la disposición 1.4 relativa a [nombre del producto] para niños pequeños del ámbito de aplicación, ya que, con el enfoque propuesto consistente en incluir una referencia a los documentos de la OMS y las resoluciones de la AMS en el preámbulo, esta disposición del ámbito de aplicación sería redundante.

En línea con nuestros comentarios para las recomendaciones 9 y 13, Costa Rica considera que es prematuro agregar la referencia a las directrices y políticas pertinentes de la OMS, así como resoluciones

relevantes de la Asamblea Mundial de la Salud (AMS) , pues el tema general de las políticas de la OMS y el mandato del Codex será considerado en la próxima sesión de la Comisión del Codex Alimentarius (CAC41) para permitir una discusión informada y decisiones, por lo tanto, Costa Rica sugiere la eliminación de dicha mención en esta Norma del Codex.

Recomendación 26: Que el CCNFSDU apruebe el siguiente párrafo introductorio para la sección de etiquetado para [nombre del producto] para niños pequeños (sección B):

Costa Rica aún no define una posición para esta recomendación.

Recomendación 27:

Que el CCNFSDU tome nota de la preferencia del GTE por la revisión de las declaraciones de propiedades nutricionales para [nombre del producto] para niños pequeños en caso de que el Codex establezca y adopte VRN para este grupo de edad. Que el CCNFSDU convenga que no debe retrasarse el proceso de revisión de esta Norma y que toda consideración sobre los VRN (si se establecen para este grupo de edad) y la finalidad de dichos VRN en las Directrices sobre etiquetado nutricional (CAC/GL 2-1985), incluida la necesidad de determinar si deberán revisarse las disposiciones relativas al etiquetado de las normas del Codex sobre alimentos para lactantes y niños pequeños en caso de que el Codex adopte VRN, deberá formar parte del mandato de un grupo de trabajo sobre los VRN. Habida cuenta de que el Comité no puede prever el resultado de ningún posible trabajo sobre los VRN para este grupo de edad, se recomienda mantener el statu quo para las declaraciones de propiedades nutricionales (y saludables): conservar la prohibición de realizar declaraciones de propiedades nutricionales y saludables en los alimentos para lactantes y niños pequeños excepto en los casos específicamente previstos en las normas pertinentes del Codex o en la legislación nacional.

Costa Rica aún no define una posición para esta recomendación.

Recomendación 28:

Que el CCNFSDU adopte el siguiente texto para la sección 9.1 sobre el nombre del producto e indique qué opción prefiere para la disposición 9.1.4, incluyendo el texto entre corchetes.

Costa Rica apoya la recomendación para los puntos 9.1.1 y 9.1.3.

En 9.1.2, Costa Rica no considera necesaria la adición de la palabra "o regional", pero no se opone a ella.

Para la sección 9.1.4 Costa Rica apoya la Opción 1 ya que aporta claridad.

En la Sección 9.1.5, Costa Rica apoya el uso del término "puede"

El texto del punto 9.1 se leería como sigue:

9.1 Nombre del producto

9.1.1 El texto de la etiqueta y toda otra información que acompañe el producto deberán estar escritos en el idioma o los idiomas apropiados.

9.1.2 El producto se denominará «[nombre del producto] para niños pequeños», tal como se define en la sección 2.1, o cualquier otra denominación apropiada que indique la verdadera naturaleza del producto, de conformidad con las costumbres del país ~~[~~o de la región~~]~~.

9.1.3 En la etiqueta se indicará claramente el origen de las proteínas que contiene el producto. ~~9.1.4 OPCIÓN 1: Dividir la disposición 9.1.4 en dos:~~

9.1.4(a) Si el origen de las proteínas~~[*]~~ es exclusivamente la leche ~~[~~de nombre del animal~~]~~, el producto podrá etiquetarse «[nombre del producto] para niños pequeños a base de ~~[~~proteína de~~]~~ leche ~~[~~de nombre del animal~~]~~».

9.1.4(b) Si el origen de las proteínas~~[*]~~ es exclusivamente ~~[~~nombre del vegetal~~]~~, el producto podrá etiquetarse «[nombre del producto] para niños pequeños a base de ~~[~~proteína de~~]~~ ~~[~~nombre del vegetal~~]~~».

~~[~~* Se aclara que la adición de distintos aminoácidos, cuando sean necesarios para mejorar la calidad de las proteínas, no impide el uso de las opciones de etiquetado anteriores.~~]~~

~~O bien OPCIÓN 2: Eliminar la disposición 9.1.4 por estar cubierta por la disposición 9.1.3.~~

9.1.5 Todo producto que no contenga leche ni ningún derivado lácteo ~~[deberá]~~ ~~[~~podrá~~]~~ etiquetarse con la expresión «no contiene leche ni productos lácteos», o una frase equivalente.

Recomendación 29: Que el CCNFSDU adopte el siguiente texto para la sección 9.2 sobre la lista de ingredientes:

9.2 Lista de ingredientes

9.2.1 En la etiqueta figurará la lista completa de los ingredientes ~~[, incluidos los ingredientes facultativos]~~, por orden decreciente de proporciones, salvo que, cuando se hayan añadido vitaminas o minerales, estos ingredientes se podrán indicar como grupos separados de vitaminas o de minerales. Dentro de tales grupos no será necesario indicar las vitaminas y los minerales por orden decreciente de proporciones.

9.2.2 Se indicará en la etiqueta el nombre específico de los ingredientes de origen animal o vegetal y de los aditivos alimentarios. ~~[~~Además, para los aditivos alimentarios, podrá indicarse opcionalmente el número del SIN.~~]~~

Costa Rica apoya la recomendación 29.

Recomendación 30: Que el CCNFSDU adopte el siguiente proyecto de texto para la sección 9.3 sobre la declaración del valor nutritivo de [nombre del producto] para niños pequeños:

9.3 Declaración del valor nutritivo La declaración de información nutricional [de [nombre del producto] para niños pequeños] deberá contener las siguientes informaciones, en el orden en que aquí se indican:

a) la cantidad de energía, expresada en kilocalorías (kcal) y/o kilojulios (kJ), y la cantidad en gramos de proteínas, carbohidratos y grasa por cada 100 g o cada 100 ml de alimento vendido, ~~[~~así como~~]~~ ~~[o]~~ por 100 ml del alimento listo para el consumo que se haya preparado de acuerdo con las condiciones indicadas en la etiqueta;

b) la cantidad total de cada vitamina y mineral indicados en el apartado 3.1.3 de la sección B, y de cualquier otro ingrediente indicado en la lista del apartado 3.2 de la sección B, por 100 g o cada 100 ml de alimento vendido, ~~[~~así como~~]~~ ~~[o]~~ por 100 ml del alimento listo para el consumo que se haya preparado según las instrucciones indicadas en la etiqueta;

c) además, se permitirá la declaración del contenido de nutrientes por ~~[~~tamaño de porción o por~~]~~ cada 100 kcal (o por 100 kJ).

Costa Rica apoya la recomendación 30.

Recomendación 31: Puesto que este documento se ha redactado antes de la celebración de la 44.ª reunión del CCFL, se recomienda que el CCNFSDU acuerde modificar el texto anterior (según sea necesario) y adopte los cambios propuestos en la citada reunión del CCFL para que dicho texto sea coherente con el texto y los resultados de los debates de la reunión del CCFL.

Costa Rica apoya la recomendación 31.

Recomendación 32: Que el CCNFSDU adopte el siguiente texto para la sección 9.5 para [nombre del producto] para niños pequeños y que presente observaciones sobre el texto que sigue entre corchetes.

Costa Rica apoya la recomendación 32.

9.5 Instrucciones de uso

9.5.1 Los productos [listos para el consumo] en forma líquida podrán utilizarse directamente o, en el caso de productos líquidos concentrados ~~[~~y productos en polvo~~]~~, deberán prepararse con agua inocua o agua que se ha vuelto inocua hirviéndola antes de suministrarlos de acuerdo con las instrucciones de uso~~. [Los productos en polvo deberían reconstituirse con agua inocua o agua que se ha vuelto inocua hirviéndola antes de la preparación.]~~ Se darán instrucciones adecuadas para la preparación y manipulación apropiadas de conformidad con las buenas prácticas de higiene.

9.5.2 En la etiqueta se darán instrucciones adecuadas para la preparación y el uso apropiados del producto, así como para su conservación y su eliminación después de su preparación, es decir que deberá desecharse el ~~preparado [~~producto~~]~~ sobrante.

9.5.3 La etiqueta deberá contener instrucciones gráficas claras que ilustren el método de preparación del producto. ~~[No se permitirán las imágenes de biberones en las etiquetas de [nombre del producto] para niños pequeños.]~~

9.5.4 ~~[~~Las instrucciones deberían incluir una advertencia acerca de los peligros para la salud que pueden derivarse de un almacenamiento, una preparación o un uso inadecuados~~]~~.

9.5.5 En la etiqueta se darán instrucciones adecuadas sobre la conservación del producto después de que se haya abierto el envase.

~~[~~9.5.6 La etiqueta de [nombre del producto] para niños pequeños deberá contener una declaración de que el producto no se introducirá antes del duodécimo mes de vida y de que deberá consumirse dentro de un régimen alimentario [diversificado] ~~[equilibrado].]~~

Recomendación 33: Que el CCNFSDU adopte el siguiente texto para la sección 9.6 para [nombre del producto] para niños pequeños y que examine el texto presentado entre corchetes en las distintas disposiciones.

Costa Rica apoya la recomendación 33 y el texto del punto 9.6 con algunos ajustes como sigue:

9.6 Requisitos de etiquetado adicionales

~~[~~9.6.1 La etiqueta de [nombre del producto] para niños pequeños no deberá contener imágenes, textos ni declaraciones~~[~~, **incluidas imágenes de biberones**,~~]~~ que puedan afectar negativamente a la práctica de la lactancia materna o desalentar dicha práctica, o que idealicen el uso de [nombre del producto] para niños pequeños. No deberán utilizarse en la etiqueta términos como «humanizado», «maternalizado» u otros términos análogos.~~]~~ **La etiqueta de [nombre del producto] para niños pequeños incluirá una declaración de que estos productos no son sucedáneos de la leche materna y no deberán presentarse como tales.**

~~[~~9.6.2~~]~~ Los productos serán etiquetados evitando cualquier riesgo de confusión entre preparados para lactantes, preparados complementarios para lactantes de más edad, [nombre del producto] para niños pequeños y preparados para usos medicinales especiales ~~[~~, **y de manera que los consumidores los distingan claramente, ~~en particular por el texto, las imágenes y los colores utilizados~~**].

Recomendación 34: Que el CCNFSDU adopte la siguiente definición para los preparados complementarios para lactantes de más edad:

Costa Rica apoya la recomendación 34.

Por preparados complementarios para lactantes de más edad se entiende todo producto especialmente fabricado para ser utilizado como parte líquida ~~[~~de un~~]~~ régimen alimentario ~~[~~progresivamente~~/~~diversificado~~]~~ de lactantes de más edad cuando se introduce la alimentación complementaria.

Recomendación 35: Que el CCNFSDU examine la siguiente propuesta de definición para [nombre del producto] para niños pequeños, incluido el texto entre corchetes.

Costa Rica apoya la recomendación 35 y con un ajuste el texto propuesto como sigue:

Por **[nombre del producto] para niños pequeños** se entiende todo producto especialmente ~~**[elaborado y]**~~ fabricado para ser utilizado como parte líquida del régimen alimentario ~~**[progresivamente]**~~ ~~[~~diversificado~~]~~ de los niños pequeños **~~[~~a fin de contribuir a las necesidades nutricionales de los niños pequeños~~]~~ ~~[cuando las ingestas de nutrientes puedan no ser suficientes para satisfacer las necesidades nutricionales].~~**

Lo anterior por cuanto podría interpretarse que una dieta progresivamente diversificada puede no ser suficiente para satisfacer los requerimientos nutricionales de los niños pequeños o que el producto puede usarse solo cuando la ingesta de nutrientes no es adecuada.

Recomendación 36: Que el CCNFSDU decida adoptar preparados complementarios para lactantes de más edad como nombre del producto para el grupo de edad de 6-12 meses (lactantes de más edad).

Costa Rica apoya la recomendación 36.

Recomendación 37: Que el CCNFSDU adopte uno de los dos nombres siguientes para el producto para niños pequeños:

Bebida preparada para niños pequeños

Bebida preparada para el niño pequeño

Costa Rica apoya ambos nombres propuestos en inglés y recomienda que el Comité considere cuál de estos nombres se traduce mejor en otros idiomas.

EL SALVADOR

El Salvador agradece el documento remitido por la Secretaría del Codex preparado por el grupo de trabajo electrónico dirigido por Nueva Zelanda, Francia e Indonesia.

Se ha revisado el apéndice 1, El Salvador presenta los comentarios del debate sobre los diferentes puntos :

Sobre el texto del anteproyecto según las recomendaciones planteadas por el GTE comenta:

- **Recomendación 1**

  1.5 Proteínas:

El Salvador apoya el contenido numeral **4 "Que se combinen las dos oraciones de la nota 6 a pie de página relativas a la evaluación clínica de los preparados a base de proteínas de la leche no hidrolizadas que contengan menos de 1,8 g de proteínas/100 kcal y los preparados a base de proteínas hidrolizadas que contengan menos de 2,25 g de proteínas/100 kcal."**

- **Recomendación 2**

  1.6 Adición opcional de ácido docosahexaenoico:

  El Salvador no apoya "**que en la nota al pie sobre la adición opcional de ácido docosahexaenoico se establezca un nivel mínimo de 13 mg/100 kcal (3,1 mg/100 kJ)."** Se propone un nivel mínimo de 16 mg/100 Kcal (3,8 mg/100 kJ.

  El Salvador apoya **"que el NSR acordado del 0,5 % del contenido total de ácidos grasos se convierta en 30 mg/100 kcal (7,9 mg/100 kJ)."**

- **Recomendación 3**

  2.4 Nivel mínimo para el contenido total de grasas:

  El Salvador apoya **"establecer un nivel mínimo para la grasa de 3.5 g/100 Kcal (0.84 g/100 Kj)"**

- **Recomendación 5**

  2.6 Azúcares distintos de la lactosa y otros carbohidratos con sabor dulce:

  El Salvador apoya **"1.0 establecer un límite del 20 % de los carbohidratos disponibles para los monosacáridos y los disacáridos distintos de la lactosa**."

- **Recomendación 7**

  2.7 Proporción de calcio / fósforo:

  El Salvador no apoya el texto de esta recomendación. Sugiere que esta relación entre calcio /fósforo es importante en la composición esencial de [nombre del producto] para niños pequeños (12 -36 meses), es importante para un equilibrio mineral entre calcio y fosforo, favoreciendo el equilibrio nutricional para un adecuado funcionamiento del organismo.

  El Salvador propone que se establezca la proporción calcio/fósforo mínimo de 1:1 y una proporción máxima de 2:1 en [nombre del producto] para niños pequeños".

- **Recomendación 8**

  2.8 Vitamina D:

  El Salvador apoya "**la adición obligatoria de vitamina D y los niveles mínimo [1,5] µg/100 kcal y máximo [4,5] - µg/100 kcal."**

- **Recomendación 9**

  3. Preámbulo

  El Salvador llego a consenso únicamente en el siguiente texto del 1er. y 3er. párrafo d**el enfoque propuesto por la Secretaría del Codex y la OMS consistente en incluir un preámbulo en la *Norma para preparados complementarios* y** ha seleccionado la expresión de los corchetes sin tachar y sugiere adición del término subrayado:

  La Comisión del Codex Alimentarius confirma la necesidad de [proteger ~~respaldar~~/reconocer] y apoyar la lactancia como un medio incomparable para proporcionar un alimento ideal para el crecimiento y el desarrollo saludables de los lactantes. Al mismo tiempo, el Codex reconoce que numerosos preparados se han elaborado o destinado al uso, cuando fuera [necesario/~~pertinente]~~, como sucedáneos de la leche materna para cubrir las necesidades nutricionales normales de los lactantes, siempre que se preparen en condiciones higiénicas y se suministren en las cantidades adecuadas.

  La presente* Norma *está dividida en dos secciones. La sección A se refiere a los preparados complementarios para lactantes de más edad (6 a 12 meses) y la sección B trata de [nombre del producto] para niños pequeños (12 a 36 meses). No se aplica a los productos regulados por la* Norma del Codex para preparados para lactantes *(CODEX STAN 72-1981).

- **Recomendación 10**

5.2.1 Punto 1.1 del ámbito de aplicación

El Salvador apoya el texto siguiente **"1.1 Esta sección de la *Norma* se aplica a los preparados complementarios para lactantes de más edad definidos en la sección 2.1, en forma líquida o en polvo**.

- **Recomendación 11**

5.2.2 Punto 1.2 del ámbito de aplicación

El Salvador apoya el texto siguiente, y selecciona el termino del corchete: **"1.2 Esta sección de la *Norma* contiene los requisitos de composición, calidad, inocuidad, [~~etiquetado~~] relativos a los preparados complementarios para los lactantes de más edad."**

El Salvador requiere mayor explicación sobre el término "Análisis" en este párrafo del ámbito de aplicación de la norma ya que la sección que se está revisando es relativa al etiquetado y no a la composición esencial.

- **Recomendación 12**

5.2.3 Punto 1.3 del ámbito de aplicación

- El Salvador apoya el texto siguiente y ha seleccionado la opción en corchetes sin tachar: **"Solo [deberán presentarse/~~se presentarán~~] como] preparados complementarios para lactantes de más edad los productos que cumplan con los criterios establecidos en las disposiciones de esta sección de la presente Norma.**

- **Recomendación 16**

5.4 Etiquetado: nombre del producto

El Salvador apoya el siguiente texto para la sección 9.1 sobre el nombre del producto (Numerales 9.1.1, 9.1.2, 9.1.3 e indica que prefiere para la disposición 9.1.4, la Opción 1, incluyendo el texto entre corchetes.)

9.1 Nombre del producto

9.1.1 El texto de la etiqueta y toda otra información que acompañe el producto deberán estar escritos en el idioma o los idiomas apropiados.

9.1.2 El producto se denominará «preparado complementario para lactantes de más edad», tal como se define en la sección 2.1, o cualquier otra denominación apropiada que indique la verdadera naturaleza del producto, de conformidad con las costumbres del país [~~o de la región~~].

9.1.3 En la etiqueta se indicará claramente el origen de las proteínas que contiene el producto.

9.1.4 OPCION 1: Dividir la disposición 9.1.4 en dos

9.1.4(a) Si el origen de las proteínas [*] es exclusivamente la leche [de nombre del animal], el producto podrá etiquetarse «preparado complementario para lactantes de más edad a base de [proteína de] leche [de nombre del animal]».

9.1.4(b) Si el origen de las proteínas[*] es exclusivamente [nombre del vegetal], el producto podrá

Etiquetarse «preparado complementario para lactantes de más edad a base de [proteína de] [nombre del vegetal]». [* Se aclara que la adición de distintos aminoácidos, cuando sean necesarios para mejorar la calidad de las proteínas, no impide el uso de las opciones de etiquetado anteriores.]

EUROPEAN UNION

European Union competence

European Union vote

This document provides specific comments on each recommendation made by the eWG Chairs in document CX/NFSDU 17/39/4

FOLLOW-UP FORMULA FOR OLDER INFANTS

Recommendation 1 (protein)

Nutrient	Current FUF Standard	IF Standard	eWG Chairs' proposal	Delegated Regulation (EU) 2016/127
Protein (g/100 kcal)	3-5,5	1,8-3	1,6-3	1,6-2,5

The EU agrees with the recommendation with respect to the minimum protein content of 1,6 g/100 kcal, which reflects the European Food Safety Authority (EFSA)'s Scientific Opinion. It concluded that the use of follow-up formula with a protein content of at least 1.6 g/100 kcal from intact cow's milk protein or intact goat's milk protein is safe and suitable for infants living in Europe with an intake of complementary foods of a sufficient quality and could be generalised to healthy infants with comparable dietary intakes living in other countries.

With respect to footnote 5 (soy protein isolates): the EU agrees with the recommendation to add a reference to non-goats milk protein, given that EFSA reviewed only the safety and suitability of follow-on formula, based on cows' milk intact protein or goats' milk intact protein, with a protein content of 1.6 g/100 kcal and provided a favourable opinion. The EU agrees with the recommendation to retain the current protein minimum of 2.25g/ 100kcal for soy protein isolates which is in line with EFSA`s advice and is consistent with the Infant Formula Standard.

With respect to footnote 6 (clinical evaluation): the EU agrees with the recommendation to introduce a requirement for clinical evaluation of formula with non-hydrolysed milk protein levels below 1,8 g/100 kcal, given that EFSA`s Scientific Opinion cannot be generalised to countries where protein intakes may be lower and/or of poorer quality. Therefore, the EU considers that the evidence remains insufficient to unconditionally warrant the lowering of the protein minimum to 1.6 g/100 kcal. However, for the sake of clarity, the EU suggests to specify in the footnote that one particular formula should be clinically evaluated for its **safety** and **suitability** by a competent national and/or regional authority.

At the same time, as noted in previous occasions, the EU would support introducing a requirement for clinical evaluation for all formulae based on hydrolysed protein (and not only those containing less than 2,25 g/100 kcal), in line with the requirements in EU legislation (Regulation (EU) 2016/127) and the advice of EFSA. In this context, it should be noted that EFSA published on 11 May 2017 a scientific guidance on the data that food business operators should make available to the Authority when submitting dossiers on formulae manufactured from protein hydrolysates.

In light of the above the following text is proposed for footnote 6:

Follow-up formula based on non-hydrolysed milk protein containing [less than 1.8 g] protein/100 kcal [(0.43 g/100 kJ)] and follow-up formula based on hydrolysed protein ~~containing less than [2.25 g protein/100 kcal] (0.54 g/100 kJ)~~ should be clinically evaluated for ***its safety and suitability*** by a competent national and/or regional authority.

Recommendation 2 (optional addition of DHA)

In previous discussions on the matter the EU had considered it prudent to require the mandatory addition of DHA to Follow-Up Formula for older infants in amounts similar to those in breast milk. This consideration was based on DHA's structural role in the nervous tissue and the retina, its involvement in normal brain and visual development, the need for the developing brain to accumulate large amounts of DHA in the first two years of life and the fact that the intake of pre-formed DHA generally results in a DHA status more closely resembling that of a breastfed infant (than the one achieved with ALA alone). In the spirit of compromise the EU agreed with the principle of voluntary addition, but stressed that, when added on a voluntary basis, DHA should be present at a level that is significant for infants.

Taking into account the agreement of CCNFSDU38 to further consider the levels for DHA based on total energy density instead of as a percentage of total fat, the EU would still support a minimum DHA level (in case of voluntary addition) of 20 mg /100 kcal, as recommended by EFSA in its opinion of 2014.

With respect to the GUL the EU agrees with the recommendation to set it at 30 mg/100 kcal to allow for a wider range of DHA levels and to ensure consistency with the Infant Formula Standard.

With respect to the footnote, the EU is of the opinion that different legal interpretations could exist on the footnote and some could argue that it refers only to the DHA/ARA and DHA/EPA ratios. For the sake of clarity, the EU would therefore propose a minor redrafting to the footnote:

If docosahexanoic acid (22:6n-3) is added to follow-up formula, arachidonic acid (20:4 n-6) contents should reach at least the same concentrations as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. Competent national

and/or regional authorities may deviate from the above conditions, **may set different levels and may require the mandatory addition of docosahexaenoic acid,** as appropriate for the nutritional needs.

FOLLOW-UP FORMULA FOR YOUNG CHILDREN

Recommendation 3 (minimum level for fat of 3.5 g/100 kcal)

The EU agrees with the recommendation of the Chairs to establish a minimum level for fat of 3.5 g/100 kcal in Follow-Up Formula for young children. This level is comparable with that found in reduced fat milk allowing the marketing of Follow-Up Formula based on semi-skimmed milk in those countries that recommend semi-skimmed milk consumption.

Recommendation 4 (Maximum level for available carbohydrates of 12.5 g/100kcal)

The EU continues to prefer establishing a maximum carbohydrate level of 12g/100kcal, as this level would ensure the nutritional integrity of the product, taking into account the composition of either full fat or semi-skimmed milk and formulas.

Recommendation 5 (Types of carbohydrates)

The EU welcomes the Chairs` proposal which clarifies the differences in definitions for sugars by replacing "sugars" with "mono-and disaccharides". With respect to the percentage limit for sugars the EU continues to support the setting of a maximum limit for mono-and disaccharides, other than lactose of 10% of available carbohydrates. As noted in the contribution to the eWG, sugar consumption can negatively influence the development of taste preferences of young children, therefore setting a lower limit of 10% of available carbohydrates would be of great importance. The EU acknowledges that there is support in the eWG to bring the limit for free sugar in line with the WHO recommendation. In this context it is worth noting that while WHO recommends limiting the intake of free sugars to less than 10% of total energy intake it also recommends further reduction to less than 5% of total energy intake for additional health benefits.

The EU also agrees with the recommendation to bring the wording in line with the WHO recommendation. In practice, for drinks, the WHO definition of "free sugars" largely covers mono- and disaccharides with the exception of lactose present in dairy products. The EU understood that the proposed reference to mono- and disaccharides encompasses all mono- and disaccharides in [name of the product], irrespective of the way they were incorporated, e.g. as mono-and disaccharides included as such, included as ingredients containing mono-and disaccharides or included during the production process (i.e. enzymatic hydrolysis of starches). The same applies to the reference that sucrose and/or fructose should not be added, unless needed as a carbohydrate source. This encompasses sucrose and/or fructose in [name of the product], irrespective of the way they were incorporated, e.g. as sucrose and/or fructose included as such (i.e. added fructose), included as ingredients containing sucrose and/or fructose (i.e. fruit juice syrups containing high amounts of fructose) or included during the production process (i.e. enzymatic hydrolysis of starches).. The footnote should ensure that all those forms of mono-and disaccharides and sucrose and/or fructose are covered.

With respect to the restrictions on the use of sweet tasting carbohydrates, the EU agrees with the Chairs` proposal. The EU understands that the wording "other carbohydrates contributing to the sweet taste of [name of product]" is comprehensive and includes non-available carbohydrates as those can contribute significantly to the sweet taste of a product. Also, as noted in the contribution to the eWG, products that are formulated as lactose-free products or products with low lactose contents could contain predominantly polysaccharides, with a sweetness level comparable to the sweetness level of glucose and lead to products with a distinctive sweet taste. Having a maximum limit for available carbohydrates to up to 12g and a limit for mono- and disaccharides other than lactose could still lead to products with a distinctive sweet taste which could potentially negatively influence the development of taste preferences of young children. As an alternative, the EU can accept that other carbohydrates, available or not available, contributing to the sweet taste of [name of product] can be included in the second sentence of the footnote to be included in the list of carbohydrates that are limited in quantity, as proposed in the text below.

The EU considers the restriction "solely" in the last sentence of the footnote to be difficult to enforce. It can be argued that substances or ingredients are added for more than solely one purpose, in order to impart sweet taste. Therefore, the EU proposes to delete "solely".

Text Proposal:

[4)] Lactose should be the preferred carbohydrate in [name of product] based on milk protein. **[Mono- and disaccharides]**, other than lactose, [**and/or other carbohydrates contributing to the sweet taste of [name of product]][, that were added as such, as constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means,]** should not exceed [~~2~~**1**0%] of

available carbohydrate. **[~~Mono- and disaccharides includes sugars naturally present in honey, syrups, fruit juices and fruit juice concentrate.~~]** Sucrose and/or fructose **[~~and/or other carbohydrates contributing to the sweet taste of [name of product]~~]** should not be added **[as such, as constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means]** **[~~and/or other carbohydrates contributing to the sweet taste of [name of product]~~]**, unless needed as a carbohydrate source. **[Other non-carbohydrate ingredients should not be added [~~solely]~~ with the purpose of imparting a sweet taste.]**

Clean version:

[4)] Lactose should be the preferred carbohydrate in [name of product] based on milk protein. Mono- and disaccharides, other than lactose, and/or other carbohydrates contributing to the sweet taste of [name of product], that were added as such, as constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means, should not exceed 10% of available carbohydrate. Sucrose and/or fructose should not be added as such, as constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means, unless needed as a carbohydrate source. Other non-carbohydrate ingredients should not be added with the purpose of imparting a sweet taste.

Recommendation 6 (Conversion of % limits of sugars)

The EU continues to prefer presenting the limit as a percentage of available carbohydrates, however, the EU can accept the Chairs' proposal to convert percentage limits to an absolute amount based on the energy density, provided the proposed way of calculation ensures a very restrictive approach.

Recommendation 7 (calcium-to-phosphorous ratio)

The EU agrees with the Chairs that there is no need to establish a calcium/phosphorus ratio in follow-up formula for young children, taking into account that phosphorous is not a key nutrient in cows' milk or a nutrient with inadequate intakes in the diet of young children, and that diets of young children are increasingly diversified providing phosphorous from other sources.

Recommendation 8 (Vitamin D)

The EU continues to support the setting of a minimum level of 1 µg/100 kcal and a maximum level of 3 µg/100 kcal which align with the levels agreed to for Follow-Up Formula for older infants in line with the pragmatic approach followed in the Committee for the mandatory addition of other micronutrients whose intakes are widely inadequate in the diet of young children.

SCOPE AND LABELLING-OLDER INFANTS (6-12 MONTHS)

Recommendation 10 (Scope-section 1.1)

As noted in the contribution to the eWG, the EU continues to support the inclusion of the statement "*It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981)*" in the scope, which would be in line with the Format for Codex Commodity Standards establishing that *"This section should contain a clear, concise statement as to the food or foods to which the standard is applicable (…)"*.

Recommendation 11 (Scope-section 1.2)

The EU can accept the Chairs` proposal that Section 1.2 of the Scope for follow-up formula for older infants be expanded to reference the labelling and analytical requirements within the Standards.

Recommendation 12 (Scope-section 1.3)

The EU agrees with the Chairs` recommendation.

As regards the wording in square brackets, the EU would prefer to use "**shall**" instead of "**should**" in order to ensure consistency with the terminology used in the labelling section of the Standard.

Recommendation 14 (Labelling-introductory paragraph)

The EU agrees with the Chairs` recommendation.

As noted in the contribution to the eWG, the EU is of the view that the Codex General Standard for the Labelling of Pre-packed Foods (CODEX STAN 1-1985) and the Guidelines on Nutrition Labelling (CAC/GL 2-1985) should be referenced in an introductory paragraph, in line with the approach followed in the Infant Formula Standard.

With regard to the inclusion of a reference to the applicability of the recommendations in the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997), in the EU a number of applications for authorisation of claims made on foods for infants and young children are pending. The EU cannot therefore provide its full views on the matter at this stage, since a decision has not yet been taken in relation to those applications. However, the EU finds the Chairs` proposal to refer to the Guidelines, as a reasonable compromise between different views in the eWG.

Recommendation 15 (NRV for infants and young children)

As noted in the contribution to the eWG, in the EU a number of applications for authorisation of claims made on foods for infants and young children are pending. The EU cannot therefore provide its full views on the revisit of nutrition claims at this stage, since a decision has not yet been taken in relation to those applications. However, the EU agrees with the Chairs` recommendation that the progress of reviewing the Standard should not be delayed. A decision to develop NRVs for infants and young children may be taken, but such work is in principle not related at this stage to the finalisation of this Standard.

The EU agrees with the Chairs` proposal to maintain the status quo for nutrition and health claims i.e. the prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in the relevant Codex Standards or national legislation.

Recommendation 16 (Name of Product)

With regard to section 9.1, 9.1.1, 9.1.2, 9.1.3, the EU agrees with the wording proposed by the Chairs.

With regard to section 9.1.4, as noted in the contribution to the eWG, the EU is supportive of retaining this provision in consistency with the Infant Formula Standard, provided that it specifically reflects that goat's milk can also be a source of protein for follow-up formula (i.e. "*If cows' (or goats') milk is the only source of protein, the product may be labelled "Follow-Up Formula for older infants based on Cows' (or goats') Milk"*).

In light of the above, the EU prefers OPTION 1 for provision 9.1.4, which clearly indicates the only source of protein (such as cows`milk, goats`milk or soy) present in the product.

With regard to section 9.1.5, the EU can support use of the word "*shall*" for consistency with the Infant Formula Standard.

Recommendation 17 (List of ingredients)

With respect to section 9.2.1, the EU agrees with the Chairs` proposal to delete the text [**including optional ingredients**] as it is already covered by the provision under section 9.2.1 and it is therefore redundant. The recommendation would also ensure consistency with the Infant Formula Standard, which is of great importance.

With respect to section 9.2.2, the EU is not convinced by the necessity to add the proposed text in square brackets, since it is not specifically mentioned in the Infant Formula Standard either. The EU would once again stress the importance to ensure consistency with the Infant Formula Standard, unless divergences are justified.

Recommendation 18 (Declaration of Nutritive Value)

The EU agrees with the Chairs' proposal to include the text "*as well as*" and delete "*or*" in section 9.3. As noted in the contribution to the eWG, both indications are useful: while nutrition information per 100 ml of the food ready for use is of most value to consumer, indication per 100 grams of the food as sold can be more relevant for health care professionals. Further to this, the proposed recommendation would also ensure consistency with the Infant Formula Standard.

Recommendation 19 (Date Marking and Storage Instructions)

The EU agrees with the Chairs' proposal to adopt any changes proposed at CCFL44 in order to be consistent with the text and outcomes of the discussions at the Codex Labelling Committee meeting.

Recommendation 20 (Information for use)

With respect to section 9.5.1, 9.5.2, 9.5.3, 9.5.4, 9.5.5, the EU agrees with the Chairs` recommendations which ensure clarity on the different requirements applicable to Follow-Up Formula for older infants.

With respect to section 9.5.6, the EU welcomes the proposal to delete the text "*not to be used as a sole source of nutrition*" and to keep the text "*older infants should receive complementary foods in addition to the formula".* As noted in the contribution to the eWG, both sentences convey the same message therefore keeping only the latter one which is more complete would be sufficient.

However, the EU continues to suggest including the following statement in section 9.5 of the Standard on Follow-Up formula for older infants: *"the decision to begin complementary feeding, including any exception to six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, based on the individual infant's specific growth and development needs".* As noted in the contribution to the eWG, a statement similar to above would stress the importance health care professionals' advice for deciding when to begin complementary feeding, including any exception to six months of age, taking into account individual infants' specific growth and development needs. It is corroborated by the Scientific Opinion of EFSA of 2009 on the appropriate age of introduction of complementary feeding (currently subject of review) and it would also ensure consistency with provision 8.6.4 of CODEX STAN 74-1981 for processed cereal-based foods for infants and young children and provision 10.2.4.1 of the Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991), where the same statement is required.

Recommendation 21 (Additional Labelling Requirements)

The EU agrees with the recommendation proposed by the Chairs which aims at ensuring that the labelling of Follow-Up Formula for older infants does not discourage breastfeeding. This principle is also reflected in a number of provisions of EU legislation as for example in Article 10 of Regulation (EU) No 609/2013, Article 6(6) of delegated Regulation (EU) 2016/127) which apply to follow-on formula and are very similar (if not identical in certain cases) to those listed in Article 9.6 of the Infant Formula Standard.

With respect to section 9.6.4, the EU strongly supports the inclusion of the following text the in the provision, in line with EU legislation (Article 6(6)3rd paragraph of delegated Regulation (EU) 2016/127): ***"and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used"***. As noted in previous occasions, it is essential to ensure that products for older infants and products for young children are clearly distinguishable. The best way to achieve this is by including in the Standard a provision clearly specifying how that should be ensured.

SCOPE AND LABELLING-YOUNG CHILDREN (12-36 MONTHS)

Recommendation 22 (Scope-section 1.1)

As noted in the contribution to the eWG, the EU continues to support the inclusion of the statement "*It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981*)" in the scope, which would be in line with the Format for Codex Commodity Standards establishing that *"This section should contain a clear, concise statement as to the food or foods to which the standard is applicable (…)"*

Recommendation 23 (Scope-section 1.2)

The EU can accept the Chairs` proposal that Section 1.2 of the Scope for follow-up formula for young children be expanded to reference the labelling and analytical requirements within the Standards.

Recommendation 24 (Scope-section 1.3)

The EU agrees with the Chairs` recommendation.

As regards the wording in square brackets, the EU would prefer to use "**shall**" instead of "**should**" in order to ensure consistency with the terminology used in the labelling section of the Standard.

Recommendation 26 (Labelling-introductory paragraph)

The EU agrees with the Chairs` recommendation.

As noted in the contribution to the eWG, the EU is of the view that the Codex General Standard for the Labelling of Pre-packed Foods (CODEX STAN 1-1985) and the Guidelines on Nutrition Labelling (CAC/GL 2-1985) should be referenced in an introductory paragraph, in line with the approach followed in the Infant Formula Standard.

With regard to the inclusion of a reference to the applicability of the recommendations in the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997), in the EU a number of applications for authorisation of claims made on foods for infants and young children are pending. The EU cannot therefore provide its full views on the matter at this stage, since a decision has not yet been taken in relation to those applications. However, the EU finds the Chairs` proposal to refer to the Guidelines as a reasonable compromise between different views in the eWG.

Recommendation 27 (NRV for infants and young children)

As noted in the contribution to the eWG, in the EU a number of applications for authorisation of claims made on foods for infants and young children is pending. The EU cannot therefore provide its full views on the revisit of nutrition claims at this stage, since a decision has not yet been taken in relation to those applications. However, the EU agrees with the Chairs` recommendation that the progress of reviewing the Standard should not be delayed. A decision to develop NRVs for infants and young children may be taken, but such work is in principle not related at this stage to the finalisation of this Standard.

The EU agrees with the Chairs` proposal to maintain the status quo for nutrition and health claims i.e. the prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in the relevant Codex Standards or national legislation.

Recommendation 28 (Name of Product)

With regard to section 9.1, 9.1.1, 9.1.2, 9.1.3, the EU agrees with the wording proposed by the Chairs.

With regard to section 9.1.4, as noted in the contribution to the eWG, the EU is supportive of retaining this provision in consistency with the Infant Formula Standard, provided that it specifically reflects that goat's milk can also be a source of protein for follow-up formula (i.e. "*If cows' (or goats') milk is the only source of protein, the product may be labelled 'name of product (for young children)' based on Cows' (or goats') Milk"*).

In light of the above, the EU prefers OPTION 1 for provision 9.1.4 which clearly indicates the only source of protein (such as cows`milk, goats`milk or soy) present in the product.

With regard to section 9.1.5, the EU can support use of the word "*shall*" for consistency with the Infant Formula Standard (and Section A of the Follow-Up Formula Standard).

Recommendation 29 (List of ingredients)

With respect to section 9.2.1, the EU agrees with the Chairs` proposal to delete the text [**including optional ingredients**] as it is already covered by the provision under section 9.2.1 and it is therefore redundant.

With respect to section 9.2.2, the EU is not convinced by the necessity to add the proposed text in square brackets, since it is not specifically mentioned in the Infant Formula Standard either. The EU would once again stress the importance to ensure consistency with the Infant Formula Standard, unless divergences are justified.

Recommendation 30 (Declaration of Nutritive Value)

The EU agrees with the Chairs` proposal to include the text "*as well as*" and delete "*or*" in section 9.3. As noted in the contribution to the eWG, leaving the choice between the two alternatives to operators could create confusion when comparing products.

The EU also agrees with the deletion of the words **"per serving size"** taking into account that the declaration of nutrients per serving size would in any case be allowed under certain conditions established in the Guidelines on Nutrition labelling (CAC/GL 2-1985), which apply anyway to (name of the product) for young children.

Recommendation 31 (Date Marking and Storage Instructions)

The EU agrees with the Chairs' proposal to adopt any changes proposed at CCFL44 in order to be consistent with the text and outcomes of the discussions at the Codex Labelling Committee meeting.

Recommendation 32 (Information for use)

The EU agrees with the proposed text for Section 9.5 which ensures consistency with the same provision proposed for Follow-Up Formula for older infants.

As noted in the contribution to the eWG, the EU is of the opinion that "information for use" provisions should not be more stringent for (name of product) for young children than what is proposed for Follow-Up Formula for older infants, or infant formula, taking into account that young children have increasingly diversified diets and that the Codex General Standard for the labelling of prepackaged foods (STAN 1-1985) applies anyway to (name of product) for young children.

Recommendation 33 (Additional labelling requirements)

The EU agrees with the recommendation proposed by the Chair which aims at ensuring that the labelling of Follow-Up Formula for young children does not discourage breastfeeding but at the same time it allows for some level of flexibility at national/regional level. The EU remains of the view that Follow-Up Formula for

young children has a different role in the diet than Follow-Up Formula for older infants which must be taken into account when laying down Standards for the product.

With respect to section 9.6.1 the EU supports the inclusion of the wording "including pictures of feeding bottles". Firstly, such graphics could lead to confusing this product with infant formula or follow-up formula, particular a high risk for illiterate consumers that may rely more on pictures than on text. Secondly, in the EU, a number of Member States recommend to not feed young children any more with bottles with teats. This ensures that young children are not delayed in the development of typical oral motor skills for this age.

With respect to section 9.6.2, the EU strongly supports the inclusion of the following text the in the provision, in line with EU legislation (Article 6(6)3rd paragraph of delegated Regulation (EU) 2016/127): ***"and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used".*** As noted in previous occasions, it is essential to ensure that products for older infants and products for young children are clearly distinguishable. The best way to achieve this is by including in the Standard a provision clearly specifying how that should be ensured.

For this reason explained before, the EU supports an additional labelling requirement that "The label shall have no text that might recommend or promote bottle feeding of the product".

PRODUCT DEFINITIONS

Recommendation 34 (Definition for Follow-Up Formula for older infants)

As noted in the contribution to the eWG, the EU would like to reiterate that Follow-Up Formula for older infants (6-12 months) and (Name of Product) for Young Children (12-36 months) can be considered as conceptually similar: they are liquid elements in the diversified diet of older infants and young children. While it is obvious that their role in the diet of infants and young children changes with time, as diets progressively diversify (i.e. the product's relative contribution to energy and nutrient requirements decreases with time), this does not mean that Follow-Up Formula for older infants are always completely different from (Name of Product) for Young Children and should therefore have a different definition, or a different name. If this approach had to be followed, then one would also have to provide different definitions/names for products for young children aged 12-18, 18-24, 24-36 months. This would be an endless exercise, and would create excessive confusion.

In light of the above the EU continues to support a broad and simpler definition, similar to the one present in the current Follow-Up Formula Standard, which would cover both products for older infants and for young children. By way of example, *"Follow-up formula means a product intended for use as a liquid part of the progressively diversified diet for older infants, when complementary feeding is introduced, and for young children".*

Recommendation 35 (Definition for Follow-Up Formula for young children)

As noted in the contribution to the eWG, the EU would like to reiterate that Follow-Up Formula for older infants (6-12 months) and (Name of Product) for Young Children (12-36 months) can be considered as conceptually similar: they are liquid elements in the diversified diet of older infants and young children. While it is obvious that their role in the diet of infants and young children changes with time, as diets progressively diversify (i.e. the product's relative contribution to energy and nutrient requirements decreases with time), this does not mean that Follow-Up Formula for older infants are always completely different from (Name of Product) for Young Children and should therefore have a different definition, or a different name. If this approach had to be followed, then one would also have to provide different definitions/names for products for young children aged 12-18, 18-24, 24-36 months. This would be an endless exercise, and would create excessive confusion.

In light of the above the EU continues to support a broad and simpler definition, similar to the one present in the current Follow-Up Formula Standard, which would cover both products for older infants and for young children. By way of example, *"Follow-up formula means a product intended for use as a liquid part of the progressively diversified diet for older infants, when complementary feeding is introduced, and for young children".*

As regards the concept of including the wording *"when nutrient intakes may not be adequate to meet the nutritional requirements of young children"* in the Standard, the EU continues to reiterate its concerns. As noted in previous occasions, this definition seems to imply that these products are necessary to tackle nutritional deficiencies: however, as EFSA noted in its advice in 2013, 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 addition, the fact that this element is not

present in the definition of Follow-Up Formula for older infants further increases confusion, taking into account that the products can be considered as conceptually similar.

PRODUCT NAMES

Recommendation 36 (Name of product for older infants)

The EU agrees with the Chairs` recommendation.

Recommendation 37 (Name of product for young children)

As noted in previous occasions, the EU is of the view that different names for products for older infants and young children would give excessive recognition to (Name of Product) for Young Children.

The EU continues to agree with the Chairs that it is essential to ensure that products for older infants and products for young children are clearly distinguishable. However, this can be better achieved by including in the Standard a provision clearly requiring operators to ensure that this is the case, and specifying how that should be ensured, as it is recommended under sections 9.6.4 and 9.6.2.

KYRGYZSTAN

With regards to the continuation of review of Codex Standard on follow - up formula by the Codex Committee on Nutrition and Food for Special Dietary Uses, planned to be held in December 2017 in Berlin, the Kyrgyz Republic would like to emphasize the crucial role of the Codex in the protection of lives and health of consumers and ensuring fair practices in food trade, protection of optimal feeding of infants and young children, including the development of standards for breast milk substitutes.

However, between the protection of consumers' health and trade interests there often occur conflicts, as well as debates over the review of the Standard on follow - up formula – where trade and commercial interests are clearly taking preference over health. Nutrition and health of infants and young children are at great risk, especially in low- and middle - income countries.

Kyrgyzstan (or the Kyrgyz Republic), which is one of lower middle-income countries, is concerned with such situation. A growing body of evidence shows that companies are cross-promoting infant formulas and follow-up formulas – this is a practice that has a negative impact on both exclusive breastfeeding and continued breastfeeding and violates the provisions of the International Code of Marketing of Breastmilk Substitutes. In Kyrgyzstan, with the aim of protection of children's health, particularly infants and young children through protection and promotion of breastfeeding and regulating the marketing of breast-milk substitutes, in 2008 there was adopted the Law on "Protection of breastfeeding and regulating the marketing of breast-milk substitutes". In Kyrgyzstan, despite improvement of situation with breastfeeding, 59 % of children under 6 months of age are still deprived of opportunities to be exclusively breastfed.

Currently, interagency working group jointly with academic sector and public organizations is developing the draft document on amendments and additions to the above Law, including labelling and marketing of the discussed products. Adoption of the Standard with the text in its current wording can hinder the undertaken measures on improvement of situation.

On the World Health Assembly 2016, the countries have adopted WHA Resolution 69.9, which clearly states that the follow-up formula and growing- up milks are breastmilk substitutes. We would like the Codex to protect our children and promote favourable environment and conditions for breastfeeding. The 39th meeting of Codex Committee on Nutrition and Food for Special Dietary Uses can change this situation through prioritization of consumers' protection, especially children, over trade and commercial interests through alignment of the standard with WHA Resolution 69.9 and the relative guidelines.

In connection with the above, the Kyrgyz Republic stresses the importance of the following issues and believes that the Committee will take constructive efforts for addressing the following 2 issues:

- The Preamble and/or the Scope for both products under discussion must make direct reference to / list WHA resolutions, especially WHA 69.9. This relates to recommendations 9, 13 and 25. We think that norms of Standards should be clear and explicit in relation to the appropriate documents/WHA resolutions in order to protect and promote optimal infant and young child feeding. We believe that WHA resolutions WHA 39.28, WHA 63.23 and WHA 69.9 must be referenced in the text or mentioned as a footnote.
- Both products, included in the Standard, function as breastmilk substitutes as their consumption displaces rather than complements breastfeeding. Hence, it is vital that these products are clearly defined as breastmilk substitutes. Definitions for products for children aged 6-12 months (recommendation 34) and for children aged 12-36 months (recommendation 35) must include wording that clearly states that the products are breastmilk substitutes.

MOROCCO

Recommendation 1:

Protein intakes for older infants:

Due to the lack of data on protein intakes in this category of children in Morocco, for the moment, (the MOH is running food intake study in old infant and young children, but the results will be available in over a year), and as the current standards review will take decades, Morocco agree to support the chair proposal, as follows: A minimum protein level of 1.6 g/100 kcal is established and that clinical evaluation is required for formula with non-hydrolysed milk protein levels below 1.8 g/ 100 kcal.

Recommendation 2:

DHA intakes for older infants:

Morocco is still supporting to set an efficient minimum level of 20mg/100Kcal, it is more appropriate for these children, with the adjunction of the arachidonic acid at the same concentration.

Recommendation 3:

Fat intake in "the name of product" for young children:

Fat is an important macronutrient for brain development in these children, as it is advising to improve the quality of fat of this product by the adjunction of unsaturated fatty acids, and knowing that brain develops rapidly during the first three years, the reduced fat cows' milk is not recommended, and we are encouraging a minimum of 04 g%kcal, in order to take the maximum advantage of this product not for the physical growth point of view by for the brain growth point of view.

Recommendation 7:

Calcium-to- phosphorous ratio in "the name of product" for young children:

For having a balanced product, and protect its' integrity, we should keep a Calcium-to- phosphorous ratio close to the one of the food which is milk. Because the adjunction of calcium with an unbalanced absorption could be at risk of kidney stones, high pressure…As the milk intake is high during this period of life, we should have a scientific evidence based recommendation ration, to ensure safety and security of this consumption in later life, before to council this ration.

Recommendation 37:

The name of the product for young children:

The two proposals include drink which make confusion with others drinks without milk, specifically when translated in French language, and because the product could be liquid or powder form, Morocco propose the name of "FORMULA FOR YOUNG CHILDREN" or "PREPARATION POUR ENFANTS EN BAS ÂGE"

NIGERIA

Recommendation 1:

Nigeria does not support the recommendation of a minimum of 1.6 g/100Kcal. Nigeria supports proposal for the adoption 1.8 g/Kcal

Rationale: The EFSA opinion, which the 38th session of CCNFSDU agreed to wait on its publication, indicated that 1.6 g/100 Kcal is applicable to countries with good alternatives sources of protein and that the guidance was specifically applicable to European countries. In developing countries especially in Africa, alternative protein sources such as grains and legumes are generally regarded as poor sources of proteins. It is based on this that we recommend the minimum level of 1.8 g/100Kcal. A footnote may be introduced to indicate that countries with good sources of alternative protein may consider a minimum of 1.6 g/Kcal.

Recommendation 9:

Nigeria supports the introduction of a preamble with the following amendment to the text. The proposed changes to the text as indicated by the strike through and bold with proposed inclusion highlighted only.

The Codex Alimentarius Commission acknowledges the need to ***[protect and support*** ~~***/recognize***~~***]*** *breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where* ***[necessary*** ~~***/ appropriate]***~~*, as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding.*

*The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account [**~~as appropriate,~~**] the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as WHA resolutions 39.28, 63.23, 69.6 and any other relevant World Health Assembly (WHA) resolutions that have been [**endorsed ~~/ supported~~**] by member states [**~~may also~~**] provide guidance to countries in this context.*

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981).

Rationale: The preamble should clearly promote and protect breast feeding practices without any ambiguity.

It is equally important that specific known WHA resolution to which countries have ratified during the World Health Assembly should be explicitly mentioned in absolute terms and provide the provision for any other WHA resolution related to these products that may be adopted in future to be applicable without the need of revisiting the standard.

Recommendation 16:

Nigeria supports proposals in option 2 on deletion of 9.1.4

Rationale: Nigeria supported deletion of 9.1.4 since 9.1.3 which require declaration of protein sources also address issues related to source of protein in the products as elaborated under the proposed clause 9.1.4.

Recommendation 37:

Nigeria supports the proposal for the product for young children name to be **formula for young children**

Rationale: For consistency and as well separate the products based on age i.e. infant formula, formula for older infant and now formula for young children.

SIERRA LEONE

Sierra Leone commend the work done by the electronic working group chaired by New Zealand, co-chaired by Indonesia and France. Sierra Leone as low income country believes that three(3) important issues need to be addressed:

1. The **Preamble and/or the Scope** for both products under discussion MUST make direct reference to / list WHA resolutions, especially WHA 69.9. This relates to recommendation 9 / recommendation 13 / recommendation 25

Recommendation 9:

Sierra Leone support the introduction of the Preamble with amendment as follows:

*The Codex Alimentarius Commission acknowledges the need to [**protect and support}** breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where [**necessary}**~~,~~ as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding.*

*The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as **WHA resolutions 39.28, 63.23, 69.6 and any** other relevant World Health Assembly (WHA) resolutions that have been [**endorsed**} by member states provide guidance to countries in this context.*

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981).

Sierra Leone believes on the promotion and protection of breast feeding practices without any ambiguity and that specific known WHA resolution to which our countries have ratified during the World Health Assembly should be explicitly mentioned in absolute terms and provide the provision for any other WHA

resolution related to these products that may be adopted in future to be applicable without the need of revisiting the standard.

Recommendation 13:

Sierra Leone strongly support this recommendation provided the text is amended as proposed in our comment recommendation 9. The objectives is to protect optimal infant and young children by promoting and protecting breast feeding practices.

Recommendation 25:

Same as Recommendation 9 and 13. WHA 69.9 must be specifically mentioned in the text or as a foot note.

2. The **Definition of** both products under discussion (aged 6-12 month and children aged 12-36 months) MUST clearly states that products are breast milk substitute. This is in line with WHA 69.9 and this explicitly states that these products are breast milk substitutes. This relate to **recommendation 34 and 35.**
3. The **Name of the product** for young children aged 12-36 months SHOULD NOT include the word 'formulated'. This relates to recommendation 37. Globally it has been accepted that these products are not necessary and therefore the name given must be neutral and contain no implied benefit/claim. **Sierra Leone** recommend that the product should simply be names 'Drink for young children' or 'Young child drink'.

SRI LANKA

We believe there are seven (7) important items that need to be addressed in the document:

1. The Preamble and/or the Scope for both products under discussion MUST make direct reference that specifically references all the relevant WHO documents, The Global Strategy on Infant and Young child feeding, the international code for marketing of breast milk substitutes and to list WHA resolutions, especially WHA 69.9 and its accompanying WHO guidance on ending the Inappropriate marketing of foods for Infant and Young children. This relates to recommendation 9 / recommendation 13 / recommendation 25. We believe that this document has to be explicit regarding appropriate documents/WHA resolutions in order to protect and promote optimal infant and young child feeding. We believe that WHA resolutions WHA 39.28, WHA 63.23 and WHA 69.9 must be referenced and at the least WHA 69.9 must be specifically mentioned in the text or as a footnote. The preamble should clearly state that these products are <u>not necessary</u> as endorsed by member states in WHA resolution 39.28 and that member states are free to refuse their entry.
2. The deletion of provision 1.4 in the scope should be reintroduced. The scope must remind regulatory authorities of the safe guards contained in the over-arching pre amble.
3. The Definitions for both the products for children aged 6-12 month and children aged 12-36 months MUST include wording that clearly states that the products are breastmilk substitutes. This relates to recommendation 34 / recommendation 35. We oppose the proposed text for the product definitions for both Follow-up formula for older infants and the product for children aged 12-36 months and we believe the definition must specifically and clearly state that these products are breastmilk substitutes. These products function as breastmilk substitutes because their consumption displaces rather than complements the intake of breastmilk. It is therefore critical that these products are clearly defined as being breastmilk substitutes.
4. The Name of the product for young children aged 12-36 months SHOULD NOT include the word 'formulated'. This relates to recommendation 37. It has globally been accepted that these products are not necessary and therefore the name given must be neutral and contain no implied benefit/claim. The product should simply be names 'Drink for young children' or 'Young child drink'.
5. The labeling section 9 must clearly specific that prohibit cross branding with infant formula and the use of nutrition, health and convenience claims is clearly prohibited.
6. Standard should clearly state that all products in powdered form are reconstituted with water not less than 70 degrees centigrade in accordance with CAC/RCP 66 -2009
7. Do not agree with the inclusion of optional ingredients, especially ingredients such as DHA that are not supported by relevant convincing scientific evidence.

AFRICAN UNION

<u>Issue: Recommendation 1:</u> That CCNFSDU agree to revise the protein requirements as follows: that a minimum protein level of 1.6 g/100 kcal is established and that clinical evaluation is required for formula with non-hydrolysed milk protein levels below 1.8 g/ 100 kcal.

Comment: **African Union** does not support the recommendation of a minimum of 1.6 g/100Kcal. We support the adoption of 1.8 g/Kcal

Rationale: The EFSA opinion, which the 38th session of CCNFSDU agreed to wait for its publication, indicated that 1.6 g/100 Kcal is applicable to countries with good alternatives sources of protein and that the guidance was specifically applicable to European countries. In developing countries for example in Africa, alternative protein sources such as grains and legumes are generally regarded as poor sources of proteins. It is based on this that we recommend the minimum level of 1.8 g/100Kcal. A footnote may be introduced to indicate that countries with good sources of alternative protein may consider a minimum of 1.6 g/Kcal.

Issue: Recommendation 2: That CCNFSDU agree that the minimum in the footnote for the optional addition of docosahexaenoic acid is set to 13 mg/100kcal (3.1 mg/100 kJ).

That the agreed GUL (Guided Upper Limit) of 0.5% of total fatty acids is converted to 30 mg/100 kcal (7.9 mg/100 kJ).

Comment: **African Union** supports the recommendation

Rationale: DHA is an important nutrient for the cognitive and vision functions during child development, hence provision of DHA is critical for early childhood development growth. It is generally known that children who are optimally breast fed usually have better cognitive development compared to those who are not breast fed and this is generally attributed to the DHA. However, despite this critical role of DHA, studies on human milk have shown varying levels depending on the food consumed, with those consuming sea food having higher levels. A minimum of 13 mg/100 Kcal to 20 mg/100 Kcal are likely to have positive impact on brain development and vision. Therefore we support the current level which is an acceptable compromise for the minimum level of DHA.

Issue: Recommendation 3: That CCNFSDU agree to establish a minimum level for fat of 3.5 g /100 kcal (0.84 g/100 kJ).

Comment: **African Union** does not support the recommendation to adopt 3.5 g/100 Kcal. We propose a minimum of 4 g/100 Kcal.

Rationale: A minimum of 3.5 g/100Kcal will translate to fat contributing 24.5 % of the energy in the product. This is low for the targeted population which should ideally get about 30 - 35 % of the energy in their diet from fat due to their increased activity. A minimum of 4 g/100 Kcal will contribute 28 % energy from fat which is close to 30 % and therefore a good compromise.

Issue: Recommendation 4: That CCNFSDU agree to establish a maximum level for available carbohydrates of 12.5 g/100 kcal (3.0 g/100kJ).

Comment: **African Union** supports the recommendation.

Rationale: The proposed minimum (12.5 g/100Kcal) will contribute 50 % of the energy of the product contributed by carbohydrates which is consistent with dietary recommendation of 50 – 60 % of energy coming from carbohydrates.

Issue: Recommendation 5: That CCNFSDU:

1. Agree to establish a limit for mono- and disaccharides, other than lactose, of 20% of available carbohydrates.

2. Agree that sweet tasting carbohydrates are restricted in accordance with the amended footnote 4 below.

3. Considers the need to limit the addition of non-carbohydrate ingredients with the purpose of imparting a sweet taste.

Comment: **African Union** supports the recommendation.

Rationale: Mono and di-saccharides contributes to increasing glycemic index. They also influence a child's feeding pattern due to sweetness, which may lead to the infant or children rejecting other nutritious foods that may not necessarily have the sweet taste impacted by the mono and di-saccharides.

Issue: Recommendation 6: That CCNFSDU agree that the percentage limit for sugars [and other carbohydrates contributing to the sweet taste] is converted to an absolute amount based on the energy density (g/ 100 kcal and g/ 100 kJ) of product for young children once a decision is made on the maximum level of available carbohydrates.

Comment: **African Union** supports the recommendation

Rationale: This will help ease the reporting of analytical results.

Issue: Recommendation 7: That CCNFSDU agree that no calcium-to-phosphorous ratio is included for [name of product] for young children.

Comment: African Union supports the recommendation

Rationale: It is generally known that cow's milk is not a good source of phosphorus. Therefore since the follow-up formula is based on cow's milk, it will be technologically difficult to achieve any of the proposed ratios. In addition, follow-up products are part of complementary feeding which will be expected to provide more phosphorous.

Issue: Recommendation 8: That CCNFSDU agree to the mandatory addition of vitamin D and minimum and maximum levels

Comment: African Union does not support this recommendation

Rationale: Vitamin D should be an optional nutrient especially for countries with a good exposure to sunlight as they will be able to synthesis vitamin D. A footnote may be considered for countries with limited sun exposure to have vitamin D as mandatory nutrient.

Issue: Recommendation 9: That

1) CCNFSDU agree to the approach proposed by the Codex Secretariat and WHO, to include a Preamble in the Standard for Follow-up Formula which includes specific reference to relevant WHO documents and WHA resolutions, noting this approach to the Preamble would replace the need to list or reference these documents and resolutions within different sections of the Standard itself.

That CCNFSDU agree to the following Preamble statement proposed by the Codex Secretariat and WHO, and select the preferred wording from that presented in square brackets:

Comment: African Union supports the introduction of a preamble in the standard and proposes changes to the text as indicated by the strike thorough and bold.

*The Codex Alimentarius Commission acknowledges the need to [**protect and support** ~~**/recognize**~~] breast-feeding as an unequalled way of providing ideal food for the healthy growth and development of infants. At the same time Codex acknowledges that numerous formulae have been produced, intended for use, where [**necessary** ~~**/ appropriate**~~], as a substitute for human milk in meeting the normal nutritional requirements of infants provided they are prepared under hygienic conditions and given in adequate amounts. In addition, various products have also been produced intended specifically for young children as they progress to a more diversified diet of family foods and these products should not discourage breastfeeding.*

*The production, distribution, sale and use of follow-up formula for older infants and [name of product] for young children should be consistent with national health and nutrition policies and relevant national/regional legislation, and take into account [~~**as appropriate**~~,] the recommendations made in the International Code of Marketing of Breast-milk Substitute (1981) and the Global Strategy for Infant and Young Child Feeding. Relevant WHO guidelines and policies as well as **WHA resolutions 39.28, 63.23, 69.6 and any** other relevant World Health Assembly (WHA) resolutions that have been [**endorsed** ~~**/ supported**~~] by member states [~~**may also**~~] provide guidance to countries in this context.*

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with [Name of Product] for Young Children (12 to 36 months of age). It does not apply to products covered by the Codex Standard for Infant Formula (CODEX STAN 72 – 1981).

Rationale: African Union notes the diverse opinions that have been expressed on the inclusion of WHO policies and resolutions in the preamble. African Union supports the view that breast feeding must be promoted and protected and that referencing specific WHA resolutions in the standard provides one of the means of achieving this objective. In this respect, the AU supports the referencing of specific WHA resolutions. AU also notes that there may be the need for more extensive discussions within the realm of the CAC to better determine how CAC should reference non-Codex document that are relevant for Codex standard in order to ensure uniformity of referencing across all Codex committees.

Issue: Recommendation 10: That CCNFSDU agree to the following statement for Section 1.1:

1.1 This section of the Standard applies to Follow-up Formula for Older Infants, as defined in Section 2.1, in liquid or powdered form.

Comment: African Union supports the proposed text.

Rationale: The statement introduces the section covering older infants.

Issue: Recommendation 11: 1.2 This section of the Standard contains compositional, quality, safety, [labelling and analytical] requirements for Follow-up Formula for Older Infants.

Comment: **African Union** supports the proposed text

Rationale: It provides for the requirements of labeling which is important in these products

Issue: Recommendation 12: That CCNFSDU agree to the following statement for Section 1.3, and select their preferred terminology (should vs shall):

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard **[should / shall]** be presented as Follow-up Formula for Older Infants.

Comment: **African Union** prefers to use of the term **'Shall'** in the statement

Rationale: The use of 'shall' makes it mandatory for the products to comply as opposed to 'should'. All products declared as follow up formula must comply with the standard.

Issue: Recommendation 13: That CCNFSDU agree to:

· include reference to WHO documents and WHA resolutions within the Preamble rather than the Scope, and that this reference be as per the recommendation of the Codex Secretariat and WHO as presented within Section 5.3 of this paper.

· delete provision 1.4 for follow-up formula for older infants from the Scope section as the proposed approach to include reference to WHO documents and WHA resolutions within the Preamble makes this provision within the Scope redundant.

Comment: **African Union** can support the recommendation provided that the text is amended as proposed in our comments in recommendation 9.

Rationale: The objective is to include a normative reference on the relevant WHA resolution in absolute terms in the preamble of the standard for the purpose of promoting and protecting breast feeding practices.

Issue: Recommendation 14: That CCNFSDU agree to the following introductory paragraph to the Labelling Section for follow-up formula for older infants (Section A):

Comment: **African Union** proposes the following amendment to the proposed text

The requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985) shall apply in follow-up formula for older infants. ***Nutrition and health claims are prohibited in foods for infants and young children****. Where nutrition and health claim* ***may be*** *provided in a relevant Codex Standards or national/regional legislation, the claims shall be done in accordance to the Guidelines on Nutrition Labelling (CAC/GL 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997).*

Rationale: To give prominence to the provision within the International code of marketing of breast milk substitutes that prohibits nutrition and health claims in infant and young children foods. In addition all the existing 5 Codex standards for products for infants and young children have prohibited nutrition and health claims including the standard for follow-up formula. Therefore emphasis on prohibition should be prioritized before giving the unlikely option of having the claims based on national/regional legislations.

Issue: Recommendation 15: A decision on the need to revisit nutrition claims on the completion of NRVs for infants and young children is not required by CCNFSDU at this point in time.

Comment: **African Union** is of the opinion that the establishment of NRV should not hold the review of this standard.

Rationale: The discussions on development of NRV for young children has not started and thus holding on to this review will lead to delays in the revision of the standard.

Issue: Recommendation 16: OPTION 2: Delete provision 9.1.4 as it is covered by 9.1.3

Comment: **African Union** supports option 2 on deletion of 9.1.4

Rationale: African Union supports deletion of 9.1.4 since 9.1.3 which require declaration of protein sources covers well the issues related to source of protein in the products as elaborated under the proposed clause 9.1.4.

Issue: Recommendation 17: **9.2.1** A complete list of ingredients ~~[including optional ingredients]~~ shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. **[The INS number of Food additives may also optionally be declared. ~~the INS number].~~**

Comment: African Union supports the recommendation with slight editorial amendment on the last sentence of 9.2.2.

Rationale: The ingredients used whether optional or otherwise must be declared and thus there will be no need to emphasize on the optional ingredients. The editorial amendment was to improve the flow of the sentence.

Issue: Recommendation 18: The declaration of nutrition information [for follow-up formula for older infants] shall contain the following information which should be in the following order:

a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold [as well as] [or] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section A and any other ingredient as listed in paragraph 3.2 of Section A per 100 grams or per 100 millilitres of the food as sold [as well as] [or] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.

Comment: African Union supports the proposed text

Rationale: It provides for declaring the nutrients in absolute values which will be easy to the consumers as opposed to having the nutrients declared per Kcal (KJ) which most consumers do not understand.

Issue - Recommendation 19: As this paper was written prior to CCFL44, it is recommended that CCNFSDU agree to modify the above text (as necessary) and adopt any changes proposed at CCFL44 to be consistent with the text and outcomes of the discussions at the Codex Labelling Committee meeting in October 2017.

Comment: African Union supports the proposed text and this is a recommendation from the competent committee on labeling, CCFL.

Issue - Recommendation 20: That CCNFSDU agree to the following text for Section 9.5 and consider the proposed rewording of provision 9.5.1

Comment: African Union supports the proposed text

Rationale: The proposed text seeks to promote good hygienic practices during preparation of the product which is critical for delivering safe food.

Issue: Recommendation 21: [9.6.4] Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes**[, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.**]

Comment: African Union supports the recommendation as revised and in particular open the square brackets as proposed for inclusion under clause 9.2.4

Rationale: Studies have shown that due to similarity of packages, some consumers sometimes get confused and end up using the wrong formula for different age group. The proposed text will ensure differentiation in packaging and labeling of different formulas thus making it easy for consumers to use the right formula at the specific age.

Issue - Recommendation 22: That CCNFSDU agree to the following statement for Section 1.1:

1.1 This section of the Standard applies to [name of product] for young children, as defined in Section 2.1, in liquid or powdered form.

Comment: The recommendation is acceptable as drafted, as this is an opening phrase to the section.

Issue - Recommendation 23: That CCNFSDU agree to the following statement for Section 1.2:

1.2 This section of the Standard contains compositional, quality, safety, [labelling and analytical] requirements for [name of product] for young children.

Comment: The recommendation is acceptable as drafted, as this is an opening phrase to the section.

Issue - Recommendation 24: That CCNFSDU agree to the following statement for Section 1.3, and select their preferred terminology (should vs shall):

1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard [**should / shall]** be presented as] [name of product] for young children.

Comment: **African Union** supports the use of the word 'Shall' as opposed to "Should"

Rationale: This will make it mandatory for the product to comply with the standard

Issue - Recommendation 25: That CCNFSDU agree:

· to include reference to WHO documents and WHA resolutions within the Preamble rather than the Scope, and that this reference be as per the recommendation of the Codex Secretariat and WHO as presented within Section 5.3 of this paper.

· to delete provision 1.4 for [name of product] for young children from the Scope section as the proposed approach to include reference to WHO documents and WHA resolutions within the Preamble makes this provision within the Scope redundant.

Comment and Rationale: Same comments and rationale as recommendation 9

Issue - Recommendation 26: That CCNFSDU agree to the following introductory paragraph to the Labelling Section for [name of product] for young children (Section B):

Comment: **African Union** proposes the following amendment to the proposed text:

The requirements of the Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985) shall apply in follow-up formula for older infants. **Nutrition and health claims are prohibited in foods for infants and young children**. *Where nutrition and health claim is provided in a relevant Codex Standards or national legislation, the claims shall be done in accordance to the Guidelines on Nutrition Labelling (CAC/GL 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997).*

Rationale: To give prominence to the provision within the International code of marketing of breast milk substitutes that prohibits nutrition and health claims in infant and young children foods. In addition all the existing 5 Codex standards for products for infants and young children have prohibited nutrition and health claims including the standard for follow-up formula. Therefore emphasis to prohibition should be prioritized before giving the unlikely option of having the claims based on national/regional legislations.

Issue - Recommendation 27: A decision on the need to revisit nutrition claims on the completion of NRVs for infants and young children is not required by CCNFSDU at this point in time.

Comment: The NRV should not hold the review of this standard

Rationale: Discussions on the development of NRV for young children has not started yet, thus holding this review will lead to delays in the revision of the standard.

Issue - Recommendation 28: OPTION 2: Delete provision 9.1.4 as it is covered by 9.1.3

Comment: **African Union** supports option 2 on deletion of 9.1.4

Rationale: Provision 9.1.3 already covers the declaration of the source of protein

Issue - Recommendation 29: **9.2.1** A complete list of ingredients ~~[including optional ingredients]~~ shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives.

[The INS number of Food additives may also optionally be declared. ~~the INS number].~~

Comment: **African Union** supports the recommendation with slight editorial amendment on the last sentence of 9.2.2

Rationale: The ingredients used whether optional or otherwise must be declared and thus there will be no need to emphasize on the optional ingredients. The editorial amendment was to improve the flow of the sentence.

Issue - Recommendation 30: The declaration of nutrition information [for follow-up formula for older infants] shall contain the following information which should be in the following order:

a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams or per 100 millilitres of the food as sold [as well as] [or] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section A and any other ingredient as listed in paragraph 3.2 of Section A per 100 grams or per 100 millilitres of the food as sold [as well as] [or] per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.

c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.

Comment: **African Union** supports the proposed text

Rationale: The text provides for declaring the nutrients in absolute values which will be easy to the consumers as opposed to having the nutrients declared per Kcal (KJ) which most consumers do not understand.

Issue - Recommendation 32: That CCNFSDU agree to the following text for Section 9.5 and consider the proposed rewording of provision 9.5.1

Comment: **African Union** supports and agree with the proposed text

Rationale: The proposed text will ensure good hygienic practices during preparation of the product and thus protect the consumers.

Issue - Recommendation 33: [9.6.4] Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes**[, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used.]**

Comment: **African Union** supports the recommendation as revised and in particular the proposed inclusion under clause 9.2.4 (in square brackets)

Rationale: Studies have shown that due to similarity of packages, some consumers sometimes get confused and end up using the wrong formula for different age group. The proposed text will ensure differentiation in packaging and labeling of different formulas thus making it easy for consumers to use the right formula at the specific age.

Issue - Recommendation 34: That CCNFSDU agree to the following definition for follow-up formula for older infants: *Follow-up formula for older infants means a product, specially manufactured for use as a liquid part of [a progressively / diversified] diet for older infants when complementary feeding is introduced*.

Comment: **African Union** supports the definition

Rationale: The definition clearly describes the product as produced.

Issue: Recommendation 35: That CCNFSDU consider the following proposal for the definition of (name of product) for young children, including the text in square brackets.

[Name of product] for young children *means a product specially* ***[formulated and]*** *manufactured for use as a liquid part of the* ***[progressively] [****diversified****]*** *diet of young children* ***[in order to contribute to the nutritional needs of young children] [when nutrient intakes may not be adequate to meet nutritional requirements]****.*

Comment: African Union can only support the proposed definition if it is amended as follows:

[Name of product] for young children means a product ~~**specially**~~ ~~**[formulated and]**~~ manufactured for use as a liquid part of the [progressively] ~~[~~diversified~~]~~ diet of young children ~~**[in order to contribute to the nutritional needs of young children] [when nutrient intakes may not be adequate to meet nutritional requirements].**~~

Rationale: According to WHO, breast milk remains the most appropriate liquid part of a progressively diversified diet for the vast majority of children between 6 and 24 months of age, once complementary feeding has begun. WHO has declared that follow-up formula are not nutritionally important. Thus the proposed definition is trying to introduce a role of follow-up formulas in nutritional status of the young children. This proposed definition will be consistent with the definition of follow-up formula for older infants

Issue - Recommendation 36: That CCNFSDU agree to adopt the name Follow-up Formula for Older Infants as the name of product for the 6 – 12 month age group (older infants).

Comment: **African Union** proposes the name to be "**Formula for older infants" and not** "Follow-up formula for older infants"

Rationale: The term, 'follow-up' is not necessary in the name of the product as it gives an impression that the product is used after a previous product category has been used. However, it should be noted that there is no compositional difference in this product and infant formula. In addition the difference in formula described under Codex standards is mainly on the age which the product may be used.

Issue - Recommendation 37: That CCNFSDU agree to either of the following two names for product for young children.

· Formulated drink for young children

· Young child formulated drink

Comment: We propose the name to be **formula for young children**

Rationale: To be consistent and separate the products based on age i.e. infant formula, formula for older infant and now formula for young children.

EU SPECIALTY FOOD INGREDIENTS

At CCNFSDU 39, agenda item 4, recommendation 2, will discuss the minimum level of DHA to be added, as an optional ingredient, to FUF for older infants (6-12 months) to meet DHA's intended effect. EU Specialty Food Ingredients believes this level should be set at 20 mg/100 kcal and therefore disagree with the proposal included in the agenda item 4 which is an insufficient amount to provide a benefit.

At CCNFSDU 37 and 38 agreement was reached on the following:

- That DHA should be an optional ingredient in FUF for older infants;
- To set a minimum level, in a footnote, for optional addition of DHA;
  - when DHA is added ARA is to be added in at least equal amounts;
  - EPA, which may occur in some LCPUFA sources, should not exceed DHA;
- To further consider the levels for DHA based on total energy density instead of as a percentage of total fat

EU Specialty Food Ingredients has provided very detailed and strong scientific substantiation and justification in its written comments which are reported in document CX/NSFDU 17/38/4-Add.1 on pages 60 to 62 of the English version.

In these written comments, EU Specialty Food Ingredients clarified the rationale as to why the **voluntary** addition of DHA/ARA in Follow-up formula for older infants is beneficial for the target population from a nutritional and normal growth point of view.

EU Specialty Food Ingredients also clearly explained the assumptions used to perform the calculations leading to a **minimum required amount of DHA of 20 mg/100 Kcal in FUF with an associated Guidance Upper Limit of 50 mg/100 Kcal**. That amount is totally **backed up by the most recent published scientific literature**. Likewise, the most recent scientific literature does suggest that the addition of ARA is making the addition of DHA more effective nutritionally and that the ratio between DHA and ARA when added together shall be a minimum of 1:1. EU Specialty Food Ingredients notes that this was the consensus wording reached at the end of the last CCNFSDU session in 2016 and that should remain the basis for a final decision at the current session.

In addition to these earlier comments made available and known to the CCNFSDU community during the electronic working group and in response to the report of the electronic working group, EU Specialty Food Ingredients would like to provide the following additional clarifications:

- Codex standards in general shall provide a unique worldwide reference to countries for regulating such standardized products. The addition of DHA and ARA being consensually agreed to remain voluntary, the revised FUF standard has to contain some global reference for such addition to make sure that such products would meet the consumer needs and expectations with regards of the presence of DHA and ARA,
- By definition, a voluntary addition defined in a Codex standard does not preclude any FUF manufacturer the freedom of using it or not in their formulas,
- The application of any Codex standard remains totally voluntary at country level
- Some countries have already recognized the benefits of voluntary addition of DHA and ARA and they require it to be 20 mg/100 kcal. Codex standards should reflect products already regulated and safe in international trade as per the Codex alimentarius dual mandate.
- EU Specialty Food Ingredients notes some comments calling for discussing in detail similar provisions for young children (section 3.2 in the standard). Should the Committee agree to this instead of accepting the current wording referring to the provisions agreed on older infants then in EU Specialty Food Ingredients view it is fairly questionable and probably quite discriminatory to consider only the provision on DHA/ARA. Should section 3.2 be reopened, EU Specialty Food Ingredients strongly believe that all the other accepted nutrient provisions shall also be open for discussion in detail to define the precise nutritional needs for young children. We understand that this would further delay the finalization of the revision of the FUF standard. While EU Specialty Food

Ingredients would be ready to contribute further to this discussion on all the other nutrients EU Specialty Food Ingredients believe that the current wording of section 3.2 is satisfactory enough for the time being.

- EU Specialty Food Ingredients is convinced that adding meaningful amounts of DHA/ARA provides a benefit for the older infant and would avoid any deceptive practices of marketing those FUF in the future.
- EU Specialty Food Ingredients can provide upon request technical data showing that the addition of DHA and ARA does no impact whatsoever the palatability of the FUF by the older infants or young children

EU Specialty Food Ingredients would like to provide again the whole set of scientific substantiation in support to the above position in the Annex below.

ANNEX

We would like to answer the comments raised in the documents CX/NFSDU 17/39/4 Add. 1 and 2.

1. **Is there precedence to establish a minimum level of addition for an optional ingredient?**

   Yes, there is precedence for an optional ingredient having a mandatory minimum level.

   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."

2. **Why is 20 mg DHA/100 kcal the amount required to achieve the intended effect?**

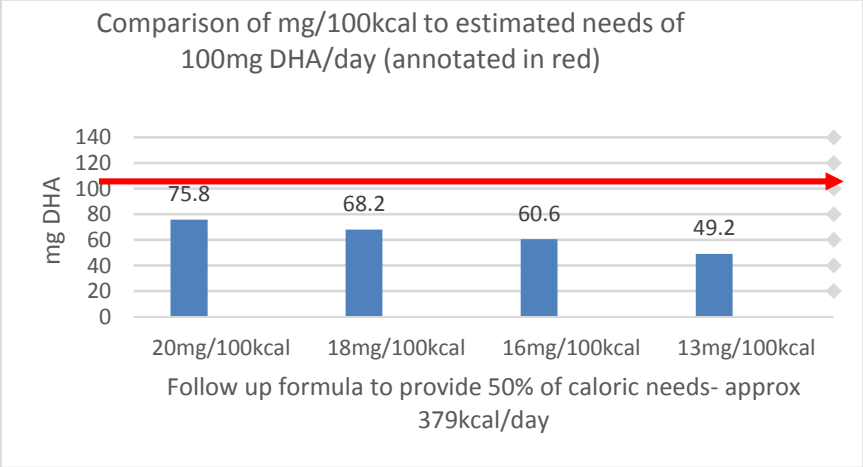
   a. Codex states that optional ingredients should be added in amounts that will provide a beneficial effect, considering levels that are reported in breast milk. Clinical research demonstrates the benefits of DHA at 20mg/100kcal, a level found in breast milk of well-nourished mothers.

      - Levels of 13mg and 16mg DHA/100kcal although reported in breast milk have not been shown to provide a beneficial effect.

   b. Scientific recommendations are consistent across the globe:

      - FAO Report 91 recommends 10-12 mg DHA/kg for older infants 6-12 months. Based on WHO median weight for age (2006) (averaged boys and girls, 6-12 months) this recommendation equates to 76-91 mg DHA/day at 6 months and 92-110 mg DHA/day at 12 months.
      - EFSA (2010) recommends 100 mg DHA per day for older infants and young children 6-24 months

   c. RASBs recommendations of approximately 100mg DHA/day in this age group have to be the starting point for the calculation of the DHA level in FUF. Establishing the minimum level of 20 mg DHA /100 kcal would result in an approximate daily intake of 60 to 75 mg DHA (as 50% of calories are provided by FUF). Although lower than established DRV by scientific authorities, it is a more meaningful amount as compared to the daily intake if the level would be only 13 mg/100 kcal (39-49 mg); see graph below.



d. In a global review of dietary intake of ARA and DHA in early life (Forsyth et al, 2016), the low-income group included 25 countries, a total population of 644 million, and an average birth rate of 34 births per 1000 population. It was estimated that, in these countries, the average daily intake of ARA and DHA from complementary foods during the period of 6-36 months, was only 8.9 and 9.6 mg/day respectively. This data indicates that each year in this group of countries, approximately 22 million infants will be at risk of LCPUFA deficiency.

e. A level of 20 mg DHA/100 is consistent with the average DHA content of human milk and the level currently found in numerous DHA containing FUF available world-wide.

3. **Why is it necessary to have a fixed minimum level for DHA (expressed in mg/100 kcal) when it is an optional ingredient?**

a. A fixed minimum is needed to ensure babies receive an efficacious amount of a nutrient and avoids the addition of ineffective amounts of ingredients and misleading label claims.

b. A minimum level is important guidance for countries that may not have access to infrastructure and resources to independently determine intakes or needs.

c. Codex provides guidance when considering the addition of optional ingredients. Codex states that the amount added should be sufficient to achieve the intended effect.

4. Should the DHA minimum level be based on the "the widest range of DHA levels within the 0.3-0.5% total fatty acid range" as suggested by the eWG Chairs in Option 1?

No, "widest range" is not an appropriate rationale because:

a. Option 1, establishing the" widest range" of DHA levels based on formula fat content permits manufacturer flexibility in formulation, but does not take into account the DHA requirements of older infants and the Codex guidance that the amount added should achieve the intended effect

b. RASBs recommendations for older infants are presented as mg per day targets of approximately 100 mg DHA/day.

c. The absolute amount of DHA intake expected from the calories consumed as FUF (typically up to 50%) is the most important consideration for achieving the target DHA intake to ensure its intended beneficial effect; not the direct translation of % total fatty acids to energy based units.

5. Is global variability of DHA intake an appropriate argument against establishing a minimum level for addition to FUF?

No, global variability of DHA intake does not mean a minimum level cannot be adopted

a. In fact, global variability is the reason that a minimum should be established in order to provide a safety net that protects the most vulnerable of populations.

b. All nutrients vary on a global scale, yet guidance on efficacious amounts can be identified via RASBs recommendations and dietary reference values.

c. Despite global variability, RASB recommendations for DHA are consistent at daily targets of approximately 100 mg for older infants.

6. Should qualifying language to the footnote regarding national deviation be provided to be certain older infants in all countries receive adequate DHA to meet recommendations.

Yes, there should be qualifying language. We recognize that there may be some countries where the intake of DHA from complementary foods is higher due to the consumption of fish. However almost all developed and developing countries are failing to meet RASB recommendations of intake of DHA (Forsyth 2016; 2017). We therefore propose to modify the last sentence on the DHA paragraph to enable national/regional nutritional deviation when scientifically substantiated.

7. What evidence supports the decision at CCNFSDU 38, when DHA is added as an optional ingredient in FUF for older infants, ARA should be added at levels equal to or greater than DHA?

Recent scientific data demonstrate the importance of ARA alone, and in combination with DHA.

a. The long-term consequences of supplying DHA without ARA have not been studied. In the past 20 years, nearly all clinical studies have combined both DHA and ARA. However, the use of formula with up to 1% DHA and no ARA would be a novel concept that has not been systematically evaluated nor with the necessary clinical trial to assess the effects, suitability and safety (Koletzko et al., 2015).

b. Providing FUF with DHA but without ARA would increase health inequalities by further disadvantaging infants whose mothers cannot breastfeed. ARA is a nutrient present in breast milk, irrelevant of the mother's diet (Brenna et al., 2007; Fu et al., 2016). Stable presence of ARA in breast milk suggests its biological importance in the developing foetus and infant.

c. Recent preclinical research indicates a need to include ARA when DHA is present to support balanced immune function (Hadley et al, 2017).

d. Dietary ARA is required in the presence of DHA to support optimal growth and development during nursing (Hadley et al, 2017).

e. Dietary ARA is essential for development of a healthy gastrointestinal system (Harauma et al, 2017)

f. ARA is a component of all cell membranes. It has a key structural and functional role in the central nervous system and is a metabolic requirement for all cells as a precursor of eicosanoids which modulate a variety of biological processes particularly those relating to cerebral, cardiovascular and immune function (Calder, 2015).

8. **Are stability and sensory qualities of a FUF product compromised with 20mg DHA/100kcal?**

No, stability and sensory qualities of FUF are not compromised at 20 mg DHA/100 kcal as evidenced by the following:

a. FUF currently on the market typically range between 13-27 mg DHA/100 kcal without apparent sensory or stability issues. Milk products are available in the USA providing up to 104mg DHA/100kcal without organoleptic issues. See table in Annex 2

b. The new Commission Delegated Regulation (EU) 2016/127 will require that DHA be added to infant formula and follow-on formula at a minimum level of 20mg DHA/100 kcal, so all manufacturers will now have to meet this level of addition in the EU.

c. DHA is currently commercially available in Mead Johnson Nutritionals products up to 19 mg DHA/100kcal and, levels of 20 mg DHA/100 kcal and higher have been tested in clinical trials (EFSA 2014b, Colombo 2016)

d. DHA and ARA ingredients have been optimized in a manner that prevents degradation of sensory and nutritional quality during storage:

- Producers of FUF have developed best practice production procedures, including nitrogen flush to reduce the presence of oxygen and thus reduce opportunity for oxidation, and ordering the addition of ingredients in a manner that best stabilizes each.
- Storage and use studies of commercial infant formulas from a variety of LCPUFA sources, with a variety of ingredients/nutrients profiles and physical formulations (i.e. powder or ready to use), varying levels and combinations of pro- and antioxidant ingredients, and regardless of total fat, have demonstrated consistent integrity of LCPUFA (Cesa et al., 2015; Siefarth et al., 2014; Kuratko et al., 2014).

9. Isn't the cost of adding DHA and ARA a limiting factor to consider when establishing a minimum level? No, efficacious level is the guiding principle for the addition of optional ingredients.

a. Addition of DHA is optional, manufacturers can choose to formulate without DHA addition and consumers can elect to purchase formulas without added DHA

b. It is the responsibility of Codex standards to establish safe and efficacious levels of nutrients for the production of FUF, cost is outside the scope of this responsibility.

References

Brenna JT, et al. (2007). Docosahexaenoic and arachidonic acid concentrations in human breast milk worldwide. Am J Clin Nutr 85:1457-64.

Brenna TJ.2016. Nutr Rev 74:329-336.

Calder PC (2015). Functional Roles of Fatty Acids and Their Effects on Human Health. JPEN J Parenter Enteral Nutr. 2015 Sep;39(1 Suppl):18S-32S. doi: 10.1177/0148607115595980.

Cesa S, Casadei MA, Cerreto F, et al. 2015. Foods 4: 487-500.

Colombo J, Jill Shaddy D, Kerling EH, Gustafson KM, Carlson SE. Docosahexaenoic acid (DHA) and arachidonic acid (ARA) balance in developmental outcomes. Prostaglandins Leukot Essent Fatty Acids. 2017 Jun;121:52-56.

COMMISSION DELEGATED REGULATION (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding

Fu Y, et al. (2016). An updated review of worldwide levels of docosahexaenoic and arachidonic acid in human breast milk by region. Public Health Nutr., 19(15):2675-87.

EFSA. 2010. Dietary Reference Values for Fats. EFSA Journal 8(3):1461

EFSA, 2013. Scientific opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. EFSA Journal, 11:3408.

EFSA, 2014a. Scientific opinion on the essential composition of infant and follow-on formulae. EFSA Journal, 12:3760.

EFSA, 2014b; Outcome of a public consultation on the draft Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on the essential composition of infant and follow-on formulae. EFSA supporting publication 2014:EN-633.

ENA, 2012. Koletzko B, Bhutta ZA, Cai W, et al., 2013. (also cited as 2012). Compositional requirements of follow-up formula for use in infancy: recommendations of an international expert group coordinated by the Early Nutrition Academy. Annals of Nutrition and Metabolism, 2013. 62:44–54.

Food and Agricultural Organization of the United Nations (FAO), 2010. FAO Food and Nutrition Paper 91.

Forsyth et al., 2016. Ann Nutr Metab 69:64-74.

Hadley KB, et al. (2017). Supplementing dams with both arachidonic and docosahexaenoic acid has beneficial effects on growth and immune development. Prostaglandins, Leukotrienes, and Essential Fatty Acids, 126:55-63.

Harauma A, et al. (2017). Effects of Arachidonic Acid, Eicosapentaenoic Acid and Docosahexaenoic Acid on Brain Development using Artificial Rearing of Delta-6-desaturase Knockout Mice. Prostaglandins, Leukotrienes, and Essential Fatty Acids, doi.org/10.1016/j.plefa.2017.10.001.

Koletzko B, et al. (2007).Dietary long-chain polyunsaturated fatty acid supplementation in infants with phenylketonuria: a randomized controlled trial. J Inherit Metab Dis; 30: 326–332.

Koletzko B, et al. (2015). Should Infant Formula Provide Both Omega-3 DHA and Omega-6 Arachidonic Acid? Ann Nutr Metab., 66:137–138

Kuratko C, Abril JR, Hoffman JP, et al. 2013. In Food Enrichment with omega-3 fatty acids. Eds Jacobsen C, et al. Woodhead Publishing Ltd Series in Food Sci, Tech, and Nutr Number 252.

Siefarth C, Serfert Y, Drusch S, et al. 2014. Foods 3:30-65.

WHO, 2006. WHO Multicentre Growth Reference Study Group. WHO Child Growth Standards: Length/height-for-age, weight-for-age, weight-for-length, weight-for-height and body mass index-for-age: Methods and development. Geneva: World Health Organization.

ANNEX 2

Examples of milk products on the market containing DHA levels from 17 mg/100 kcal to 104 mg/100 kcal without organoleptic and stability issues

Company	Brand	DHA mg/100kcal	ARA mg/100kcal
Infant formula and follow-up formula			
Mead Johnson	Enfamil A+	19.7mg DHA/100kcal	39.5 mg ARA /100kcal
Danone	Dumex Precinutri	20.0mg DHA/100kcal	20.0 mg ARA /100kcal
Reckitt Benckiser	Enfagrow Premium Transition	17mg DHA/100kcal	34mg ARA /100kcal
Friesland Campina	Frisola Prestige	19.5 mg DHA/100kcal	23.4 mg ARA/100 kcal
NTUC Fairprice cooperative	FairPrice Gold Newborn Infant Formula Milk	23.4 mg DHA/100 kcal	23.4 mg ARA/100 kcal

Additional products targeting children above 3 or whole family and containing DHA			
Horizon	Organic fat free milk	35.5mg DHA/100kcal	N/A (product targeting the whole family)
FairLife	Superkids 2% reduced fat milk	104mg DHA/100kcal	N/A (product targeting children above 3)
The Mead Johnson product Enfamil A+ as a percentage of total fatty acids provides 0.35% DHA and 0.69% ARA. Mead Johnson provided DHA and ARA containing formula for the DIAMOND randomized controlled trials. DHA was added at higher levels of 0.64% and 0.96% compared to the standard product and these did not report sensory issues (See Colombo 2016 for study design and outcomes)			

Shelf life of the DHA and ARA containing formula are between 12 to 18 months stored in aluminium tin cans, with a modified atmosphere and the residual oxygen at 3% or below.

Fairlife low 2% reduced fat milk is a refrigerated product with a shelf life of 110 days.