

CODEX ALIMENTARIUS COMMISSION **E**



Food and Agriculture
Organization of
the United Nations



World Health
Organization

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Agenda Item 3

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

Thirty-fourth Session

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**DRAFT REVISION OF THE GUIDELINES ON FORMULATED SUPPLEMENTARY FOODS FOR
OLDER INFANTS AND YOUNG CHILDREN (CAC/GL 8-1991)**

(Comments at Step 6 of the procedure)

Comments from:

BOTSWANA
EUROPEAN UNION
MALAYSIA
MEXICO
NIGERIA
THAILAND

ISDI - International Special Dietary Foods Industries

BOTSWANA

Botswana would like to thank Ghana and USA for spearheading the revision of these guidelines. In line with Botswana previous comments (33NFSDU) we would like to propose the following amendments:

SECTION 1: PURPOSE

Capitalize each word as follows: ...'Older Infants and Young Children.'

SECTION 2: SCOPE:

Delete..... 'and include but not limited to porridges containing cereals, ready-to- use products and food-based home fortificants'.

Rationale: The phrase is wordy with undefined and confusing terms such as 'porridges'

SECTION 3 DESCRIPTION

3.1 Substitute the last sentence with the following: 'These foods are specifically formulated based on the nutritional requirements of older infants and young children.'

Rationale: Most local diets are nutritionally adequate. The Global Strategy on infant and young child feeding recommends the use appropriate local foods for complementary feeding.

3.4 Complementary feeding period: Add at the end the following sentence 'Complementary feeding with these formulated complementary foods should start at the age of 6 months with continued breastfeeding up to 24 months of age.¹

Footnote:¹ 'Beyond the age of 24 months the need for formulated complementary foods has not been demonstrated for healthy young children. Extended use of formulated complementary foods beyond 24 months can lead to obesity and increased risks of other non-communicable diseases.

SECTION 4: SUITABLE RAW MATERIALS AND INGREDIENTS

4.2.2: Last sentence of paragraph (b) substitute 'CAC/STAN 192-1995' with 'CODEX STAN 192-1995'.

SECTION 5: TECHNOLOGIES FOR AND EFFECT OF PROCESSING

Change the heading so as to read as follows: '**PROCESSING TECHNOLOGIES AND THEIR EFFECTS**'

Rationale: The phrase 'Technologies for effects of processing' is considered ambiguous

5.2.3: add 'appropriate' before 'prolonged' since the required boiling time for ingredients differ.

Rationale: The desired effects of processing are not the same for all ingredients.

Proposed New Section 5.6: **Prohibition of partially hydrogenated fats and irradiated products and ingredients:**

5.6.1 The use of partially hydrogenated fats for these products is prohibited

5.6.2 The product and its components shall not have been treated by ionizing radiation.

Rationale: Based on precautionary principle and in line with the Codex Standard for Cereal Based Complementary Foods (CODEX STAN 074-1981. Rev 1-2006, Section 3.1.2.

Proposed new Section 5.7: Prohibition of GM products and ingredients

5.7.1 The product and its components shall be free from genetically modified ingredients.

Rationale: Based on precautionary principle to protect the vulnerable infants and young children. There are still a lot of controversies with regards to the safety of GM foods.

SECTION 6.NUTRITIONAL QUALITY

Section 6: Change the heading back to 'FORMULATION'

Rationale: The contents under the heading are on formulations and not nutritional quality.

6.1.3 Delete the whole paragraph.

Rationale: The manufacturer's feeding instructions should be followed as the products are of a wide range. Some could be in the form of liquid, solid and may require different measurements. The feeding volume and frequency of normal complementary foods depend on the age of the child. The contents of this paragraph do not fit well with the description of complementary foods. Lipid based products are either ingredients for fortification of complementary foods or are usually used as therapeutic products under medical prescription exclusively for severely malnourished children

6.4.2: Delete 'Error! Bookmark not defined'.

6.4.3: Delete 'Error! Bookmark not defined'

6.5.1 Substitute the text in square brackets with 'If sugars (Nutritive sweeteners) are used they should not exceed 10% by weight'

Rationale: There should be a limit of use based on the Global Strategy for Diet, Physical Activity and Health.

SECTION 8: HYGIENE

8.1: First line: Substitute 'Standard' with 'Guidelines' because these are Codex guidelines and not standards.

SECTION 10: LABELING

10.1: To read as follows 'It is recommended that the labelling of Formulated Complementary Foods for Older Infants and Young Children be in accordance with the Codex General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses (CODEX STAN 146-1985), and the Guidelines on Nutrition Labelling (CAC/GL2-1985). There should not be nutrition and health claims or any idealizing pictures or text permitted on the label. There should be clear instructions to ensure that the product is not used before six months of age or used inappropriately (i.e. in a bottle).

Rationale: Nutrition and health claims will undermine the recommended practices on optimal infant and young child feeding including breastfeeding and the use of appropriate home-made complementary foods.

Proposed new sub section 10.2.5 Allergens: There should be a declaration of allergens on all labels.

Rationale: It is a critical public health intervention.

General comment: These Guidelines have all the characteristics of a Codex product standard. It is difficult to differentiate the products covered under these guidelines and those under the standard for Cereal Based complementary foods. Botswana therefore suggests that these guidelines be combined with the said Codex standard so as to have Part A, B and C of one standard for Complementary foods.

EUROPEAN UNION

In view of the upcoming discussions, the European Union (EU) would like to send in particular the following comments for consideration:

ANNEX - TABLE

The EU believes that the vitamins and minerals listed in the table should be limited to those for which deficiency is most frequently found in older infants and young children. For the sake of consistency, the names used for the vitamins and minerals listed should be in accordance with the ones used in the Standard for Infant Formula and Formulas for Special Medical Purposes intended for Infants.

The EU would suggest using the Reference Nutrient Intake (RNI) in the Annex as it is intended to meet the requirements of the majority of the population.

MALAYSIA

6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS

6.5 Carbohydrates

Paragraph 6.5.1

Malaysia supports to retain the current text as in square brackets. This is due to the fact that the ingredients used in Supplementary Foods are very diverse, and as such the amount of nutritive sweeteners required will

vary for the different products to make the product palatable to children. Therefore, Malaysia reiterates our proposal to remove the square brackets as follows:

“6.5.1 Starch is likely to be a major constituent of many Formulated Complementary Foods. To ensure that its energy value is realized, this starch should be provided in a readily digestible form. Guidance on increasing the digestibility of starches is given in Section 5. {If nutritive sweeteners are used, they should be used sparingly.}”

MEXICO

COMENTARIOS GENERALES:

1. En las secciones 4.2, 6.2 y 6.4, México solicita la aclaración de la definición de “Contenido energético” y “Densidad energética”, ya que en español son conceptos diferentes. En la versión en inglés se utiliza “energy density”, y en la traducción se usa “contenido energético” de manera indistinta. En caso de que estos términos sean diferentes, solicitamos tomar en cuenta las siguientes definiciones:

Densidad energética

La densidad energética de un alimento o de una bebida se define como la cantidad de energía que contiene este por unidad de peso (kilocalorías por gramos, kcal/g; kilojoules por gramos, kJ/g). Es decir, es la cantidad de energía que aporta un alimento por cada gramo de peso. Los valores extremos de la densidad energética están representados por el agua (0 kcal/g y por la manteca de cerdo (9.0 kcal/g).

Referencia: Pardío J. *La densidad energética de la dieta como adyuvante en la prevención y manejo de la obesidad*. Editorial Médica Panamericana, 1ª edición, 2010.

Contenido energético

El contenido energético, se refiere a la cantidad de kJ o kcal que contiene los productos preenvasados. Esta declaración nutrimental tiene que ser obligatoria en la etiqueta de los productos preenvasados. La declaración sobre el contenido energético debe expresarse ya sea en kJ (kcal) por 100 g o por 100 ml, o por porción en envases que contengan varias porciones, o por envase cuando éste solo contiene una porción.

Referencia: NORMA Oficial Mexicana NOM-051-SCFI/SSA1-2010, Especificaciones generales de etiquetado para alimentos y bebidas no alcohólicas preenvasados-Información comercial y sanitaria. México.

2. México solicita la revisión de los pies de página del documento REP12/NFSDU ANEXO IV debido a que no presentan un orden numérico y faltan algunos de ellos, por ejemplo: los pies de página número 7 y 13 se encuentra en dos páginas con distintos textos y se cita el pie de página número 11 pero no aparece en el texto.

DIRECTRICES SOBRE PREPARADOS ALIMENTICIOS COMPLEMENTARIOS PARA LACTANTES DE MÁS EDAD Y NIÑOS PEQUEÑOS

(en el trámite 5 del procedimiento)

DOCUMENTO REP12/NFSDU ANEXO IV	COMENTARIOS DE MÉXICO
<p>3. DESCRIPCIÓN</p> <p>3.3 Por «niños pequeños» se entienden los niños desde la edad de mayores de 12 meses hasta la edad de tres años (los 36 meses de edad).</p>	<p>Se sugiere que la definición de «niños pequeños» sea corregida, debido a que los niños de 12 meses de edad quedan considerados en la definición 3.2 «lactantes de más edad», quedando el texto como sigue: “Por «niños pequeños» se entienden los niños mayores de 12 meses hasta los 36 meses de edad.”</p>
<p>4.2 Otros ingredientes</p> <p>Podrán utilizarse otros ingredientes, incluidos los que se enumeran a continuación, para mejorar la calidad nutricional o la aceptabilidad del preparado alimenticio complementario, siempre que puedan obtenerse fácilmente y se haya demostrado su idoneidad y seguridad para el fin previsto.</p> <p>4.2.1 Carbohidratos digeribles</p> <p>Se puede acrecentar la densidad energética el contenido energético de los preparados alimenticios complementarios mediante la adición de carbohidratos digeribles.</p>	<p>Ver punto 1 de los COMENTARIOS GENERALES, en relacionado a la terminología de “Contenido energético” y “Densidad energética”.</p>
<p>4.2.2 Aditivos alimentarios y aromas</p>	

<p>Solamente Los aditivos alimentarios y los aromas incluidos en la Norma del Codex para alimentos elaborados a base de cereales para lactantes y niños pequeños (CODEX STAN 074-1981, REV. 1-2006) y en la Norma del Codex para alimentos envasados para lactantes y niños (CODEX STAN 73-1981), pueden utilizarse <u>o estar presentes por transferencia de las materias primas</u>, en los preparados alimenticios complementarios hasta los límites máximos indicados en dichas normas, <u>en consonancia con las condiciones establecidas en las mismas</u>.</p> <p>Solo los aditivos alimentarios citados en esas normas podrán estar presentes en los alimentos que se incluyen en estas Directrices, como consecuencia de su transferencia a partir de materias primas u otros ingredientes (incluidos aditivos alimentarios) utilizados para producir el alimento, con sujeción a las siguientes condiciones:</p> <p>–a) que la cantidad de aditivo alimentario presente en las materias primas u otros ingredientes (incluidos los aditivos alimentarios) no exceda de la dosis máxima especificada; y</p> <p>–b) que el alimento al que se transfiere el aditivo alimentario no contenga dicho aditivo en una cantidad mayor que la que se introduciría mediante el uso de las materias primas o ingredientes con arreglo a unas buenas prácticas de fabricación, en consonancia con las disposiciones relativas a la transferencia de aditivos que figuran en el preámbulo de la Norma general para los aditivos alimentarios (CAC/STAN 192-1995).</p>	<p>Con el objetivo de hacer consonancia con los documentos citados, se propone la siguiente redacción para simplificar el texto y que se entienda que se deben elaborar bajo las mismas condiciones todos los productos que abarcan dichas normas CODEX STAN 074-1981, REV. 1-2006 y CODEX STAN 73-1981:</p> <p>“Solamente los aditivos alimentarios y los aromas incluidos en la Norma del Codex para alimentos elaborados a base de cereales para lactantes y niños pequeños (CODEX STAN 074-1981, REV. 1-2006) y en la Norma del Codex para alimentos envasados para lactantes y niños (CODEX STAN 73-1981), pueden utilizarse <u>o estar presentes por transferencia de las materias primas</u>, en los preparados alimenticios complementarios hasta los límites máximos indicados en dichas normas, <u>en consonancia con las condiciones establecidas en las mismas</u>.”</p>
<p>5. TECNOLOGÍAS PARA LA ELABORACIÓN Y SUS EFECTOS</p> <p>5.1 Tratamiento preliminar de las materias primas</p> <p>5.1.3 Desgerminación: 5.1.3.1 Cuando se considere necesario y adecuado, se debería contemplar la posibilidad de desgerminar el trigo, el maíz, la soja y otros cultivos con el fin de reducir el contenido en fitatos.</p>	<p>Con el objetivo de homologar el formato de la numeración de este punto se sugiere el siguiente cambio, eliminando el numeral 5.1.3.1 y dejando directamente el texto en el numeral 5.1.3, como sigue:</p> <p>“5.1.3 Desgerminación: Cuando se considere necesario y adecuado, se debería contemplar la...”</p>
<p>6.2 Energía</p> <p>6.2.1 La Densidad energética El contenido energético de una mezcla de cereales y legumbres molidos y de harinas desgrasadas de semillas oleaginosas en el peso en seco es relativamente bajo <u>respecto al ingrediente sin desgrasar</u>.</p> <p>6.2.2 Podrá aumentarse la densidad energética el contenido energético del alimento durante la elaboración mediante: la adición de ingredientes ricos en energía (esto es, grasas y aceites o carbohidratos digeribles) o la elaboración de las materias primas y los ingredientes básicos según se indica en la sección 5.</p> <p>6.2.3 la densidad energética El contenido energético del preparado alimenticio complementario deberá ser de, como mínimo, 4 kcal por gramo en el peso en seco.</p>	<p>Ver punto 1 de los COMENTARIOS GENERALES, en relacionado a la terminología de “Contenido energético” y “Densidad energética”.</p> <p>Para tener mayor claridad en el párrafo 6.2.1 se sugiere agregar el siguiente texto:</p> <p>“...en seco es relativamente bajo <u>respecto al ingrediente sin desgrasar</u>.”</p>

<p>6.4 Grasa</p> <p>6.4.1 La incorporación de grasas o aceites en los preparados alimenticios complementarios sirve para incrementar <u>la densidad energética</u> el contenido energético y la cantidad de ácidos grasos esenciales así como para reducir el volumen total del alimento consumido.¹⁰ Es conveniente que al menos el 20% de la energía derive de la grasa.</p>	<p>Ver punto 1 de los COMENTARIOS GENERALES, en relacionado a la terminología de “Contenido energético” y “Densidad energética”.</p>
<p>6.5 Carbohidratos</p> <p>6.5.1 El almidón es probablemente un constituyente principal de muchos preparados alimenticios complementarios. Para tener la seguridad de que su valor energético se aprovecha, este almidón deberá suministrarse en forma fácilmente digerible. En la sección 5, se indica el modo de aumentar la digestibilidad de los almidones. [Si se emplean edulcorantes nutritivos, ello debería hacerse con poca frecuencia.]</p> <p>6.5.2 Las fibras <u>dietéticas</u> alimentarias y otros carbohidratos no absorbibles son fermentados parcialmente por la flora intestinal para dar ácidos grasos de cadena corta, ácido láctico y etanol, que subsiguientemente pueden ser absorbidos y metabolizados. El aumento de la ingestión de fibras <u>dietéticas</u> alimentarias¹² incrementa el volumen de las heces, puede causar flatulencia y disminuye el apetito. La cantidad de fibra puede reducir también el contenido energético de los preparados alimenticios complementarios. Las fibras <u>dietéticas</u> alimentarias pueden afectar también a la eficiencia de absorción de importantes nutrientes de las raciones alimenticias de contenidos marginales de nutrientes. El contenido de fibra <u>dietética</u> alimentaria del preparado alimenticio complementario no deberá rebasar por tanto los 5 g por 100 g en el peso en seco.</p>	<p>México solicita aclaración de porque el texto del numeral 6.5.1 “Si se emplean edulcorantes nutritivos, ello debería hacerse con poca frecuencia” debe incluirse ya que no es claro, cuál es la intención del texto si es limitar el consumo de azúcares o de orientar sobre su uso, para lo cual se sugeriría estén en la sección 6.1 de Aspectos Generales.</p> <p>Además, con base en la regulación nacional, los azúcares son denominados como tal debido a que son alimentos utilizados como ingredientes en la formulación de preparados alimenticios complementarios. Por lo tanto, el término “azúcares” ya no es sustituido por el término “edulcorante nutritivo”.</p> <p>Sugerimos cambiar en toda la sección 6.5.2 el término “Fibras alimentarias” por “Fibras dietéticas” que es el término más adecuado.</p>
<p>6.6 Vitaminas y minerales</p> <p>6.6.1 Fijación de niveles para la adición de vitaminas y minerales</p> <p>6.6.3 Selección de vitaminas o minerales para la adición de nutrientes</p>	<p>México sugiere mantener pendiente la sección 6.6 con sus numerales, en función de los avances de la revisión en curso del documento Anteproyecto de revisión de los Principios Generales del Codex para la Adición de Nutrientes Esenciales a los Alimentos (CAC/GL 9-1987), con el objetivo de que ambos textos sean acordes.</p>
<p>7. CONTAMINANTES</p> <p>7.1 Residuos de plaguicidas</p> <p>Los productos deberán prepararse con especial cuidado, de conformidad con las buenas prácticas de fabricación, a fin de que los residuos de los plaguicidas que puedan ser necesarios para la producción, almacenamiento o elaboración de las materias primas o los ingredientes del producto final se eliminen por completo o bien, si ello es técnicamente imposible, se eliminan en la mayor medida posible. Estas medidas deberán tener en cuenta la índole específica de los productos respectivos y el grupo específico de la población al que están destinados. <u>En concordancia con lo especificado en la Norma General del Codex para los Contaminantes y las Toxinas presentes en los Alimentos y Piensos (CODEX STAN 193-1995).</u></p>	<p>Sugerimos que se incluya una referencia a la Norma General del Codex para los Contaminantes y las Toxinas presentes en los Alimentos y Piensos (CODEX STAN 193-1995), con el objetivo de que sea una guía al momento de utilizar el documento en revisión, quedando la redacción de la siguiente manera:</p> <p>“...sustancias farmacológicamente activas. <u>En concordancia con lo especificado en la Norma General del Codex para los Contaminantes y las Toxinas presentes en los Alimentos y Piensos (CODEX STAN 193-1995).</u>”</p>

<p>7.2 Otros contaminantes</p> <p>El producto deberá estar exento de residuos de hormonas y antibióticos, determinados mediante métodos de análisis aprobados, y estar también prácticamente exento de otros contaminantes, en particular, de sustancias farmacológicamente activas. <u>En concordancia con lo especificado en la Norma General del Codex para los Contaminantes y las Toxinas presentes en los Alimentos y Piensos (CODEX STAN 193-1995).</u></p>	<p>Sugerimos que se incluya una referencia a la Norma General del Codex para los Contaminantes y las Toxinas presentes en los Alimentos y Piensos (CODEX STAN 193-1995), con el objetivo de que sea una guía al momento de utilizar el documento en revisión, quedando la redacción de la siguiente manera:</p> <p>“...sustancias farmacológicamente activas. <u>En concordancia con lo especificado en la Norma General del Codex para los Contaminantes y las Toxinas presentes en los Alimentos y Piensos (CODEX STAN 193-1995).</u>”</p>
<p>8. HIGIENE</p> <p>8.2 Los ingredientes y el producto final se prepararán, envasarán y conservarán en condiciones higiénicas y deberán cumplir las disposiciones de los textos del Codex pertinentes¹³, <u>incluyendo el Código de prácticas de higiene para alimentos poco ácidos y alimentos poco ácidos acidificados envasados (CAC/RCP 23-1979) y al Código de prácticas de higiene para alimentos poco ácidos elaborados y envasados asépticamente (CAC/RCP 40-1993)</u></p>	<p>Considerar la inclusión de las normas Código de prácticas de higiene para alimentos poco ácidos y alimentos poco ácidos acidificados envasados (CAC/RCP 23-1979) y al Código de prácticas de higiene para alimentos poco ácidos elaborados y envasados asépticamente (CAC/RCP 40-1993), a fin de que queden más claras las prácticas de higiene de estos productos que pueden caer dentro de los descritos en cada una de las normas arriba mencionadas, además de las normas mencionadas en el pie de página 13, quedando de la siguiente manera:</p> <p>“...en condiciones higiénicas y deberán cumplir las disposiciones de los textos del Codex pertinentes¹³, <u>incluyendo el Código de prácticas de higiene para alimentos poco ácidos y alimentos poco ácidos acidificados envasados (CAC/RCP 23-1979) y al Código de prácticas de higiene para alimentos poco ácidos elaborados y envasados asépticamente (CAC/RCP 40-1993).</u>”</p>
<p>10. ETIQUETADO</p> <p>10.1 Se recomienda que el etiquetado de los preparados alimenticios complementarios para lactantes de más edad y niños pequeños se ajuste a las disposiciones estipuladas en la Norma general del Codex para el etiquetado y declaración de propiedades de los alimentos preenvasados para regímenes especiales (CODEX STAN 146-1985), <u>Norma general para el etiquetado de los alimentos preenvasados (CODEX STAN 1-1995)</u>, las Directrices para el uso de declaraciones nutricionales y saludables (CAC/GL 23-1997) y las Directrices sobre etiquetado nutricional (CAC/GL 2-1985). <u>Además de considerar lo aplicable de la Norma para alimentos envasados para lactantes y niños (CODEX STAN 73-1981) y la Norma para alimentos elaborados a base de cereales para lactantes y niños pequeños (CODEX STAN 74-1981)</u></p>	<p>Consideramos que la CODEX STAN 146-1985 no debería hacerse referencia ya que estos productos no se consideran para un régimen especial y en su lugar referir a la Norma general para el etiquetado de los alimentos preenvasados (CODEX STAN 1-1995), quedando el texto de la siguiente manera:</p> <p>“...disposiciones estipuladas en la <u>Norma general para el etiquetado de los alimentos preenvasados (CODEX STAN 1-1995)</u>...”</p> <p>A fin de complementar lo mencionado en la sección 10. ETIQUETADO, se considera necesario que se mencione lo aplicable de la Norma para alimentos envasados para lactantes y niños (CODEX STAN 73-1981) y la Norma para alimentos elaborados a base de cereales para lactantes y niños pequeños (CODEX STAN 74-1981), quedando el texto como sigue:</p> <p>“<u>Además de considerar lo aplicable de la Norma para alimentos envasados para lactantes y niños (CODEX STAN 73-1981) y la Norma para alimentos elaborados a base de cereales para lactantes y niños pequeños (CODEX STAN 74-1981).</u>”</p>
<p>10.2 Deberán aplicarse además las disposiciones obligatorias siguientes:</p> <p>10.2.3 Declaración del valor nutritivo</p> <p>La declaración de los datos del contenido energético y</p>	<p>Sugerimos agregar “100g o 100 ml o por envase, si el en-</p>

<p>nutritivo en la etiqueta o el etiquetado deberá incluir la siguiente información expresada por 100 g <u>o 100 ml o por envase, si el envase contiene una sola porción</u> de preparado alimenticio complementario tal como se vende o se distribuye así como también por toma de alimento lista para el consumo:</p> <p>(a) El valor energético, expresado en kilocalorías y kilojules</p> <p>(b) Las cantidades de proteínas, carbohidratos y grasas, expresados en gramos</p> <p>(c) Además de toda otra información nutricional exigida por la legislación nacional, la cantidad total <i>por toma del preparado alimenticio complementario listo para el consumo</i> de cada vitamina y mineral añadidos en conformidad con la sección 6.6, expresada en unidades del sistema métrico.</p>	<p>vase contiene una sola porción” de acuerdo a las Directrices sobre Etiquetado Nutricional, CAC/GL 2-1985 para contemplar también a los alimentos en presentación líquida.</p>
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NIGERIA

Section 5 ~~TECHNOLOGIES FOR EFFECT OF PROCESSING~~

Nigeria is of the opinion to change the heading to read as follows:

“PROCESSING TECHNOLOGIES AND THEIR EFFECTS”

Justification: The phrase “Technologies for effects of processing” is ambiguous

New Section:

Nigeria proposed inclusion of two new sections: i.e. section 5.6 and 5.7 presented as follows:

5.6: Prohibition of irradiated products and ingredients:

5.6.1 The product and its components shall not have been treated by ionizing radiation. The use of partially hydrogenated fats for these products is prohibited.

Justification: This recommendation was based on precautionary principle. This is also referenced in the Cereal Based Standards (CODEX STAN 074-1981. Rev 1-2006, Section 3.1.2.

5.7: Prohibition of GM products and ingredients

5.7.1 The product and its components shall be free from genetically modified ingredients.

Justification: This recommendation was made based on precautionary principle to protect the vulnerable group of infants and young children. There is still a lot of controversy with regards to GM foods.

6.5 Carbohydrates:

6.5.1 Starch is likely to be a major constituent of many Formulated Complementary Foods. To ensure that its energy value is realized, this starch should be provided in a readily digestible form.

Guidance on increasing the digestibility of starches is given in Section 5. ~~{If nutritive sweeteners are used, they should be used sparingly}~~ **they should not exceed 10% by weight}**

Justification: There should be a limit of use, based on the Global Strategy for Diet, Physical and Health. Also the phrase “should be used sparingly” does not give much guidance.

8. HYGIENE

8.1 It is recommended that the products covered by the provisions of this ~~Standard~~ **Guidelines** be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice – General Principles of Hygiene (CAC/RCP 1-1969) and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

Justification: This is a Guideline and not a Standard

10. LABELLING

Nigeria proposes inclusion of a **new section; 10.2.5**

10.2.5 Allergens

There should be a declaration of allergens on all labels.

Justification: This is to serve as a public health interventions.

THAILAND

Thailand would like to express our appreciation for the effort of Ghana for preparing the Guidelines on Formulated Complementary Foods for Older Infants and Young Children. We would like to propose our comments as follows:

I General comments

- 1) The term “gram” and its SI unit symbol “g” are used in different places, so we would like to propose that they should be correctly used in accordance with the recommendations of the [International System of Units \(SI\)](#).
- 2) All footnotes in the document should be amended to the comprehensive sources of references which correspond to the texts.

II Specific comments

Section 6 NUTRITIONAL COMPOSITION AND QUALITY FACTORS

- 6.1 General Aspects

- 6.1.1, the first bullet

- 1) Energy should be considered and identified in the formulation, so the term “energy” should be added to the first bullet.
- 2) Since the selection of raw materials and ingredients for the formulation should also consider macronutrient and micronutrient requirements. It is proposed to add a new bullet identifying “macronutrient and micronutrient requirements of infant and young children” after the first bullet.

Hence, Section 6.1.1 should be read as follows:

“6.1.1 The selection of raw materials and ingredients for the formulation of Formulated Complementary Foods for Older Infants and Young Children should be made having regard to the provisions in Sections 4 and 5 and taking into account the following aspects:

- **energy and** *nutrient content of the local diet;*
- **macronutrient and micronutrient requirements of infant and young children**
- *dietary habits and infant feeding practices;*
- *other socio-economic aspects as determined by the national authorities dealing with nutrition;*
- *availability and quality of raw materials and ingredients*

- 6.1.3

To be clear and avoidance of confusions, it is proposed that the term “product” in the first sentence should be replaced with “formulated complementary foods” as follow:

6.1.3 Ten to fifty grammes of the ~~product~~ formulated complementary foods, when prepared according to the instructions,...

6.5 Carbohydrates

- 6.5.1

In principle, nutritive sweeteners should not be used in these products to ensure that infants and young children will not addict to the sweet taste from sweeteners.

However, we agree that if nutritive sweeteners are used, they should be used sparingly. Consequently, a square bracket should be removed from the last sentence of 6.5.1.

Hence, this section should be read:

“Starch is likely to be a major constituent of many Formulated Complementary Foods. To ensure that its energy value is realized, this starch should be provided in a readily digestible form. Guidance on increasing the digestibility of starches is given in Section 5. ~~¶~~ If nutritive sweeteners are used, they should be used sparingly.~~¶~~”

Section 10 LABELLING

- 10.2.4 Instruction for use

- 10.2.4.5

We are of the opinions that sugars should not be specified in this section, as it may encourage to use sugar and will stimulate addition of sweet taste in children. This sentence should be read as follows;

“10.2.4.5 For Formulated Complementary Foods to which fats, ~~sugars~~ or other digestible carbohydrates should be added during preparation”

ANNEX

TABLE

In order to make progress of the work further, it is needed to improve and revise the table to be a comprehensive resource for a user of the document. Thus, we would like to propose some amendments and comments on the table as follows:

1. In the final texts, 1st and 3rd columns should be retained; meanwhile 2nd column on the 100% of the EAR should be deleted, as it may cause confusion.
2. Clear descriptions for nutrients with no identified value of 70% of RNI (such as Copper, Manganese and Phosphorus) should be provided.
3. The footnotes should provide clear description in order to make the table more understandable.

ISDI - International Special Dietary Foods Industries

The International Special Dietary Foods Industries (ISDI) represents at Codex Alimentarius the associations of manufacturers of special dietary foods and has been actively involved in the development of relevant Codex Standards and Guidelines.

ISDI is generally welcoming the work handled by Ghana to review these guidelines, but would like to understand better at this stage the consequences of the changes made on the document.

As far as we understand the Terms of References (2009 CCNFSDU), we do not see any item related to amending the overall purpose of these types of foods.

This means that while the name has been changed from “supplementary” to “complementary” to reflect on the period of feeding and not anymore on the intention of feeding, the very aim of providing these specific foods should still be transferred adequately in the text.

ISDI does not see the current description clarifying this aspect.

The reason for revising the Guidelines was based on the need to appropriately consider the malnourished population and ISDI questions whether the goal has been fulfilled.

For clarification matter, ISDI would like to highlight the following:

- In the scope of the document, ISDI would suggest:
 - Deleting the examples “ ~~and include but are not limited to porridges containing cereals, ready to use products and food based home fortificants~~” in order to highlight the generic scope of the guidelines. The scope simply needs to exclude what is not covered.
 - Add the reference to the exclusion of “ **infant formula and formulas for special medical**

purposes intended for infants, follow-up formula” in the core text and review accordingly the footnotes.

- In the Description section, ISDI would suggest specifying that:
 - **Processed cereal based foods and canned baby foods are excluded.**
 - These foods are specifically formulated with appropriate nutritional quality to provide additional energy and nutrients to complement the family foods derived from the local diet by providing those nutrients which are either lacking or are present in insufficient quantities **in order to prevent a deterioration of nutritional status of those most at risk by meeting their additional needs.**

These comments are made in order to be aligned with the Scope of the Guidelines and avoid confusion

The description in the current document is too generic and could correspond to products developed under Standards for processed-cereals based foods and canned baby foods (=fortified foods providing lacking nutrients). As a consequence, additional precision is needed to define what is the ultimate goal of these products.

It is also important to keep the spirit of these guidelines that was at the beginning to support countries to develop products based on local raw material fulfilling nutritional local gaps.

Below additional detailed comments on specific sections of the text:

Title: GUIDELINES ON FORMULATED COMPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN (REP 12/NFSDU Appendix IV)

CONSOLIDATED TEXT PROPOSED BY GHANA AFTER EWG (without footnotes)	ISDI COMMENTS
<p>2. SCOPE</p> <p>The provisions of these Guidelines apply to Formulated Complementary Foods for Older Infants and Young Children as defined in Section 3.1 below and include but are not limited to porridges containing cereals, ready to use products and food-based home fortificants. Micronutrient supplements, infant formula and formulas for special medical purposes intended for infants, follow-up formula, processed cereal based foods¹, and canned baby foods² are not covered by these Guidelines.</p> <p>These Guidelines should be used in accordance with the Global Strategy for Infants and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001).</p> <p>¹ Codex Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981, rev. 12006)</p> <p>² Codex Standard for Canned Baby Foods (CODEX STAN 73-1981)</p> <p>³ According to the WHO, 2002, Complementary Feeding, Report of the Global Consultation appropriate complementary feedings should start from the age of six months with continued breast feeding up to two years or beyond ; refer also to WHO 2003 Guiding Principles for Complementary feeding of the breastfed child, WHO 2005 Guiding principles for feeding non-breastfed</p>	<p>COMMENT</p> <p>The scope shall be generic and not introduce particular examples. The scope should only highlight what is excluded.</p> <p>To that purpose, ISDI would add the reference to the exclusion of “ infant formula and formulas for special medical purposes intended for infants, follow-up formula” in the core text and review accordingly the footnotes.</p>

<p>children 6-24 months of age.</p> <p>Footnote: Codex Standard on follow-up formula (CODEX STAN 156-1987)</p> <p>Footnote: Codex Standard on infant formula and formulas for special medical purposes intended for infants (CODEX STAN 72-1981, Revision 2007)</p>	
<p>3. DESCRIPTION</p> <p>3.1 Formulated Complementary Foods for Older Infants and Young Children means foods that are suitable for use during the complementary feeding period excluding processed cereal based foods and canned baby foods. These foods are specifically formulated with appropriate nutritional quality to provide additional energy and nutrients to complement the family foods derived from the local diet by providing those nutrients which are either lacking or are present in insufficient quantities in order to prevent a deterioration of nutritional status of those most at risk by meeting their additional needs.</p>	<p><u>COMMENT</u></p> <p>ISDI suggests these additions in order to be aligned with the Scope and avoid confusion.</p> <p>The description in the current document is too generic and could correspond to products developed under Standards for processed-cereals based foods and canned baby foods (=fortified foods providing lacking nutrients). As a consequence, additional precision is needed to define what is the ultimate goal of these products.</p> <p>It is also important to keep the spirit of these guidelines that was at the beginning to support countries to develop products based on local raw material fulfilling nutritional local gaps.</p>
<p>4.1.5 Fats and Oils</p> <p>4.1.5 Fats and Oils</p> <p>4.1.5.1 Fats and oils can be incorporated in adequate quantities as technologically feasible for the purpose of increasing the energy density of the product. Care must be taken to avoid the addition of oxidized fat which will adversely affect nutrition, flavour and shelf life. Such care is important for fat-containing ingredients (e.g., oil seed flours and oil seed protein products, fish meals, and fish protein concentrates) as well as fats and oils.</p>	<p><u>COMMENT</u></p> <p>Editorial</p>
<p>5.5.2 Enzymatic Predigestion</p> <p>5.5.2.1 With this process the milled or ground basic ingredients (cereals, pulses, and oilseed flours) can be processed in the presence of water and appropriate enzymes under continuous stirring until the mixture acquires the desired fluidity. In the case of the use of amylase, starch molecules are split into dextrins and reducing sugars. After raising the temperature to inactivate the enzyme, the slurry is dried and comminuted to flour or to small flakes to allow for greater nutrient density in the product as consumed.</p>	<p><u>COMMENT</u></p> <p>Editorial</p>
<p>6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS</p> <p>[...]</p>	<p><u>COMMENT</u></p> <p>In order to be aligned with the “lipid-based” and not giving particular product examples</p>

<p>6.1.3 Ten to fifty grammes of the product, when prepared according to the instructions, is considered a reasonable quantity which an older infant or young child during the complementary feeding period can ingest easily in one feeding and who may receive two or more feedings per day, depending on age. The range in amount per feeding allows for the various types of Formulated Complementary Foods. The lower part of the range applies to products with higher energy density (e.g., lipid-based products) whereas the upper part of the range would apply to products with lower energy density (e.g., porridges containing cereals carbohydrates-based products).</p>	
<p>6.3 Proteins</p> <p>6.3.1 Mixtures of cereals, legumes, pulses and/or oilseed flours, can constitute an appropriate source of proteins, provided that the proteins in the Formulated Complementary Food satisfy the criteria below. Protein quality can also be improved by the inclusion of fish products, milk and milk products and/or other animal source foods.</p> <p>6.3.2 The Protein Digestibility Corrected Amino Acid Score (PDCAAS)^{7,8,9} should not be less than 70 per cent of that of the WHO amino acid reference pattern for children from 2 – 5 years.</p> <p>6.3.3 If, for technical reasons, the PDCAAS digestibility of a protein cannot be determined, the protein quality should be measured by biological assays. Alternatively, the protein quality may be calculated from published data on essential amino acid patterns of dietary proteins and their digestibility.</p> <p>6.3.2: <i>The chemical index of the added protein shall be equal to at least 80 % of that of the reference protein (casein), or the protein efficiency ratio (PER) of the protein in the mixture shall be equal to at least 70 % of that of the reference protein. In all cases, the addition of essential L-amino acids shall be permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose.</i></p> <p>6.3.4 The addition of methionine, lysine, tryptophan or other limiting amino acids, solely in the L-form should be contemplated only when, for economic and technological reasons, no mixture of vegetable and/or animal proteins makes it possible to obtain an adequate protein quality (see 6.3.2).</p> <p>6.3.5 Taking into account the preceding</p>	<p><u>COMMENT</u></p> <p>ISDI suggests using the text of the Processed cereal based foods Standard. Why should the guidelines be more restrictive than Standards considering the targeted food types?</p> <p>ISDI would propose the following changes, to put in place the suggested modified provisions 6.3.2 and 6.3.3, considering among others that these provisions may be a burden for developing countries.</p>

<p>considerations, the energy from protein¹⁰ should not be less than 6 % of the total energy from the product and typically should not exceed 15%¹¹</p>	
<p>6.4 Fat</p> <p>[...]</p> <p>6.4.2 The level of linoleic acid (in the form of glycerides) should not be less than 333 mg per 100 kcal or 1.6 g per 100 g of dry product and the fat or oil used in the production of Formulated Complementary Foods should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.</p>	<p><u>COMMENT</u></p> <p>6.4.2 – Levels for linoleic acid and alfa linolenic acid.</p> <p>ISDI questions the rationale for 333mg? What is the calculation?</p>
<p>6.5 Carbohydrates</p> <p>6.5.1 Starch is likely to be a major constituent of many Formulated Complementary Foods. To ensure that its energy value is realized, this starch should be provided in a readily digestible form. Guidance on increasing the digestibility of starches is given in Section 5. [If nutritive sweeteners are used, they should be used sparingly.]</p> <p>6.5.2 Dietary fibres and other non-absorbable carbohydrates are partially fermented by the intestinal flora to produce short-chain fatty acids, lactate and ethanol which may subsequently be absorbed and metabolized. Increasing the intake of dietary fibres increases stool bulk, may cause flatulence and decrease appetite. Fibre load also can reduce the energy density of Formulated Complementary Foods. They also may affect the efficiency of absorption of important nutrients from diets with marginal nutrient contents. The dietary fibre content of the Formulated Complementary Food should therefore be reduced to a level not exceeding 5 g per 100 g on a dry weight basis</p>	
<p>6.6 Vitamins and Minerals Nutrients</p> <p>6.6.1 Setting levels for the addition of vitamins and minerals</p> <p>6.6.1.1 The decision to add vitamins and minerals Nutrients to a Formulated Complementary Food should take into account local conditions including the nutrient contribution to the diet from local foods, vitamins and minerals provided by national programs, food processing technologies applied and the nutritional status of the target population as well as the requirements stipulated by national legislation and the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL</p>	<p><u>COMMENT</u></p> <p>For consistency ISDI would suggest to change (vitamin and minerals) for (Nutrients), with consequential changes.</p>

<p>9-1987).</p> <p>6.6.1.2 If the dietary intake data for the target population is available, they can be used to determine appropriate levels for the addition of vitamins and/or minerals to ensure a low prevalence of either inadequate or excessive nutrient intakes using available assessment or monitoring tools.</p>	<p>Editorial</p>
<p>10. LABELLING</p> <p>[...]</p> <p>10.2.4 Instruction for use</p> <p>10.2.4.1 The label should indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product. In addition, the label shall include a statement indicating that the decision when precisely to introduce formulated complementary feeding, including any exception to six months of age, should be made in consultation with a health worker, based on the individual infant's specific growth and development needs. Additional requirements in this respect may be made in accordance with the legislation of the country in which the product is sold.</p> <p>10.2.4.2 Directions as to the preparation and use of the food shall be given; preferably accompanied by graphical presentations.</p> <p>10.2.4.3 The suggested number of feedings per day should be indicated.</p> <p>10.2.4.4 In the case that addition of water is needed, the directions for the preparation shall include a precise statement that:</p> <p>(a) where the food contains non-heat-processed basic ingredients, the food must be adequately boiled in a prescribed amount of water;</p> <p>(b) where the food contains heat-processed basic ingredients:</p> <p>(i) the food requires boiling, or (ii) can be mixed with boiled water that has been cooled.</p> <p>10.2.4.5 For Formulated Complementary Foods to which fats, sugars or other digestible carbohydrates should be added during preparation, the instructions for use shall identify appropriate sources and indicate the amounts of the ingredients to be added. In such situations, fats and oils with an appropriate essential fatty acid ratio should be recommended.</p>	<p><u>COMMENT</u></p> <p>ISDI would favour the use of the original text in the current Guidelines:</p> <p>Directions for use shall include a statement that only the amount of food sufficient for one meal should be prepared at one time.</p> <p>10.2.4.7</p> <p>“Feeding occasion” does not appear as the correct expression</p> <p>“Left over foods should be discarded” – the current sentence could be misunderstood.</p> <p>The original text of the current Guidelines covers in the most appropriate way what is intended to be covered by the wording proposed in the latest version of Ghana’s document.</p> <p>10.2.4.7 The label should also include a statement that Formulated Complementary Foods are to be consumed in addition to the daily diet family foods and breast milk/breast milk substitutes.</p>

<p>10.2.4.6 Directions for use shall include a statement that only an amount of food sufficient for one feeding occasion should be prepared at one time. Foods not consumed during the feeding occasion should be discarded, unless consumed within a period as recommended by the manufacturer under the instructions of use.</p> <p>10.2.4.7 The label should also include a statement that Formulated Complementary Foods are to be consumed in addition to the daily diet family foods and breast milk/breast milk substitutes.</p>	
<p>Annex</p> <p>TABLE</p> <p>The reference INL98 values listed in the Table provide a guide for selection and amounts of vitamins and minerals to be added to a Formulated Complementary Food. The suggested total quantity of each of these vitamins and/or minerals contained in a daily ration of the Formulated Complementary Food is at least 70% of INL98.</p>	<p><u>COMMENT</u></p> <p>See section 6.6</p> <p>ISDI considers that there is need to assess the Annex taking into account WHO work which is on going.</p> <p>There is need to provide general principles for establishing nutrient levels to be added to Formulated Complementary Foods instead of prescriptive values based on RNI or EAR. When values are updated at the FAO/WHO level, the table in annex would need to be updated as well.</p> <p>This is not a smooth and simple procedure.</p> <p>ISDI would recommend the deletion of the table and that a reference be made to FAO / WHO values.</p>

ANNEX

TABLE

The reference INL98 values listed in the Table provide a guide for selection and amounts of vitamins and minerals to be added to a Formulated Complementary Food. The suggested total quantity of each of these vitamins and/or minerals contained in a daily ration of the Formulated Complementary Food is at least 70% of INL98.

VITAMINS AND MINERALS	REFERENCE¹⁴ NUTRIENT INTAKE (RNI) or Individual Nutrient Levels⁹⁸ (INL⁹⁸)	ESTIMATED¹⁵ AVERAGE REQUIREMENT (100% of the EAR)	70% of RNI¹⁶
Vitamin A µg retinol equivalent	400	286	280
Vitamin D ¹⁷ µg	5	5	
Vitamin E mg (α-Tocopherol)	5	4	3.5
Vitamin C mg	30	25	21
Thiamine mg	0.5	0.4	0.35
Riboflavin mg	0.5	0.4	0.35
Niacin mg NE	6	5	4.2
Vitamin B ₆ mg	0.5	0.4	0.35
Folate µg DFE	150	120	105
Vitamin B ₁₂ µg	0.9	0.7	0.63
Calcium mg	500	417	350
Iron mg ¹⁸	11.6, 5.8, 3.9	11.6, 5.8, 3.9	8.1, 4.1, 3.4
Zinc mg ¹⁹	8.3, 4.1, 2.4	6.9, 3.4, 2.0	5.8
Iodine µg	90	64	63
Copper mg ²⁰	0.34	0.34	
Selenium µg	17	14	11.9
Vitamin K µg	15	15	10.5
Biotin µg ¹⁸	8	8	5.6
Pantothenic acid mg ¹⁸	2	2	
Magnesium mg ¹⁸	60	60	
Manganese mg ²¹	1.2	1.2	
Phosphorus mg ¹⁹	460	460	