CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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

Agenda Item 6 **CX/NFSDU 11/33/8**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Thirty third Session

Bad Soden am Taunus, Germany

14 – 18 November 2011

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

Prepared by electronic Working Group chaired by Ghana

Governments and interested international organizations are invited to submit comments on the above document at Step 3 in writing preferably by email to the Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, Fax +39-06-5705-4593, e-mail codex@fao.org with copy to Mr Georg Müller, Federal Ministry of Food, Agriculture and Consumer Protection, Rochusstraße 1, 53123 Bonn, Germany, Fax: +49 (228) 99 529 49 65, e-mail: ccnfsdu@bmelv.bund.de by **15 October 2011**.

Charge to the Electronic Working Group by the 32nd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses

At the 32nd session of the CCNFSDU, the Committee agreed to establish an Electronic Working Group chaired by Ghana, working in English, to redraft of the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 08-1991) for circulation at step 3 and for consideration by the next session of the Committee, taking into account written comments and the discussion at the current session.

The Committee also agreed to establish a physical working group, chaired by Ghana and the United States of America, and working in English, French and Spanish, which would meet immediately prior to the 33rd session to consider the revised document and comments at Step 3.

Background

The Committee recalled that at its 30th Session, it was agreed that an Electronic Working Group led by Ghana be established to revise proposals on revision of the *Codex Guidelines on Formulated Supplementary Foods for Older Infants and Young Children* (CAC/GL 8-1991). The revision was to take in to consideration comments made at the 30th Session.

The delegation of Ghana introduced the revised project document and explained the revisions made by the Electronic Working Group

Rationale for the revision

The Delegation of Ghana explained that since the 1991 Guidelines were published, new international, evidence-based recommendations regarding energy requirements and nutrient needs from Complementary Foods including Formulated Complementary Foods, for older infants and young children have been revised. In addition, Formulated Complementary Foods have expanded in recent years from porridges to several types of food-based products. The title of the Guidelines currently uses the term “Supplementary”, however, WHO uses the term “Complementary” in preference to “Supplementary” for foods used in addition to breast

milk or breast milk substitutes. WHO defines complementary foods as solid to semi-solid foods given to older infants and young children (from 6 to 2 years of age) in addition to breastmilk or breast milk substitutes (Alinorm 10/33/26 para 110).

Thus the main purpose of the proposed revision is to update the Guidelines with regard to nutritional aspects of Formulated Complementary foods for older infants and young children, based on relevant science-based recommendations. The aspects to be covered by the new work as stated in the project document (Appendix VI, Alinorm 10/33/26) are to:

a) **A**mend the name and content of the guidelines to reflect current terminology.

b) **R**evise energy and nutrient densities and recommended serving sizes and daily quantity of Formulated Complementary Foods for older infants and young children.

c) **S**trengthen the Guidelines on the importance of key ingredients.

d) **U**pdate the Guidelines on effective processing methods to reduce or eliminate anti-nutrients

e) **A**mend labeling provisions regarding the use of complementary foods

The Committee agreed (Alinorm 10/33/26, para 120) that the main aspects to be considered should include the title, scope and content of the guidelines as stated in sections 2,3,4,5,6, and 9 and the Annex. The Committee also agreed that recently developed guidelines (2008) on complementary feeding in infants and young children 6-23 months of age from WHO and UNIICEF, be considered during the revision of the Guideline.

Circulation of draft document to the EWG

The draft revised document was sent to the EWG in March 2010 and comments were received by June 2010. The following members of the EWG submitted comments on the first draft which was circulated: *Argentina, Australia, Bolivia, Brazil, China, EU (European Union), Germany, Ghana, Mexico, New Zealand, Switzerland, United States of America, ISDI* (International special dietary Foods Industry) *and Sight and Life.*

The revised draft document was sent for a second round of comments on July 2010 and comments were received by August 2010. Responses were received from the following: *Argentina, Australia, Bolivia, European Union, Germany, Ghana, Japan, Switzerland, United States of America, IACFO, ISDI and IDF.*

Based on responses to the second draft, a revised draft guidelines was circulated at step 3 keeping in mind that there were still areas that had not been resolved by the EWG. The comments received were compiled in CX/NFSDU 10/32-Add.1 for discussion at the 32nd session of CCNFSDU. Member countries and Observers who submitted comments at step 3 included: *Argentina, Botswana, Brazil, Canada, Chile, China, European Union, Indonesia, Malaysia, Philippines, South Africa, United States of America, World Food Program (WFP), International Baby Friendly Action Network (IBFAN) and (ISDI)*. Other comments were submitted as CRDs by Thailand, Mexico, Confederation Des Industries Agroalimentaires De ***L'UE,*** Kenya and Nigeria.

Majority of the comments were generally supportive of the proposed revision. However an area that generated the most comment was on the title and the scope to be covered by the revised draft document.

The draft was tabled for discussion at the 32nd session of CCNFSDU. Comments received during the plenary session were on the title, scope, use of the terminology "complementary" vs "supplementary". Discussions on the draft guidelines were recorded in the Report of the 32nd session of the CCNFSDU (REP 11/NFSDU, para 75-89)

After extensive discussion, the Committee agreed that the title should refer to "formulated complementary foods". Thus the title and description as reproduced below were agreed upon.

> **Title**: "*Guidelines on Formulated Complementary foods for Older Infants and Young Children"*
>
> **Description:** *Formulated Complementary Foods "means foods suitable for use during the complementary feeding period. These foods are specifically formulated with improved nutritional quality. They can be used as a supplement to local diet to provide those nutrients which either are lacking or are present in insufficient quantities"*

The Committee was unable to discuss the document further as a result of time constraints. The committee agreed that an EWG chaired by Ghana, working in English would re-draft the Guidelines, taking the written comments and the discussions at the 32nd session in to consideration and to be presented for consideration at the next session.

The Committee also agreed to establish a physical working group, chaired by Ghana and the United States of America, and working in English, French and Spanish, to meet immediately prior to the 33rd session to consider the revised document and comments at Step 3.

Comments from the 32nd session were taken into consideration in revising the draft guidelines which was circulated to the EWG in May 2011. A first round of comments was received in June-July 2011 from 19 members of the EWG (Bolivia, Brazil, Australia, Ethiopia, European Union, China, UK, Germany, Japan, Kenya, New Zealand, Switzerland, Uruguay, United States, Mauritius, Canada, IBFAN, ISDI and IDF).

These comments were carefully studied and as much as possible taken in to consideration in the revision of the document.

The revised draft Guidelines were sent for a second round of comments on June 30, 2011. Comments were received from 12 EWG members by July 2011: Bolivia, Brazil, European Union, New Zealand, Switzerland, Uruguay, United States, Canada, International Special Dietary Foods Industries (ISDI), International Dairy Federation (IDF), ESPGHAN, and Global Alliance for Improve Nutrition (GAIN). The comments received were thoroughly studied and as much as possible we taken into consideration in the revision of the draft Guidelines.

The draft revised Guidelines follows.

In comparison with the 1991 Guidelines, all new texts are underlined and in italics. Proposed deletions are in strike-through texts. Texts for which there appear to be no consensus have been put in square brackets for further discussion by the Physical Working Group or at the 33rd session of the CCNFSDU.

Timelines for Electronic Working Group

Proposed schedule:

Step	***Deadline***
Registration of interested parties	7 April 2011
1st Circulation of Draft to EWG members	2 May 2011
Submission of comments on 1st Draft by EWG members	3 June 2011
2nd Circulation of Draft document to EWG members	30 June 2011
Submission of comments on 2nd Draft by EWG members	30 July 2011
Submission of the final draft to the Codex Secretariat	30 August 2011

DRAFT FOR EWG DISCUSSION

GUIDELINES ON FORMULATED SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN (CAC/GL 08-1991)[1],

Title:

GUIDELINES ON FORMULATED *COMPLEMENTARY* ~~SUPPLEMENTARY~~ FOODS FOR OLDER INFANTS AND YOUNG CHILDREN ~~(CAC/GL 08-1991)~~[1]

1. PURPOSE

To provide guidance on nutritional and technical aspects of the production of Formulated *Complementary* ~~supplementary~~ Foods for older infants and young children as defined in Section 3.1, including:

i. Formulation of such foods, based on the nutritional requirements of older infants and young children;

ii. Processing techniques;

iii. Hygienic requirements;

iv. Provisions for packaging;

v. Provisions for labelling and instructions for use.

2. SCOPE

The provisions of these Guidelines apply to Formulated *Complementary* ~~Supplementary~~ Foods for Older Infants and Young Children as defined in Section 3.1 below *and include but are not limited to cereal-based porridges, ready-to-use products and food-based home fortificants*. *Micronutrient powders are not covered by these Guidelines*.

3. DESCRIPTION

3.1 **Formulated *Complementary*** ~~Supplemented~~ **Foods for Older Infants and Young Children** means foods [**that are]** suitable for use during the *complementary feeding* ~~infant's weaning~~ period. ~~and for feeding young children as a supplement to breastmilk or breastmilk substitutes **or** other food available in the country where the product is sold. They are not suitable for use for infants before the beginning of the weaning period~~. These foods *are specifically formulated with improved nutritional quality. They can be used as a supplement to local diet to* provide those nutrients which either are lacking or are present in insufficient quantities. ~~in the basic staple foods.~~

3.2 ~~The term **o** *Older infants*~~ means persons from the age of 6 months ~~6th month~~ and not more than 12 months of age.

3.3 ~~The term **y** *Young children*~~ means persons from the age of 12 months up to the age of three years (36 months).

3.4 Complementary feeding period *means the period when older infants and young children transition from exclusive feeding of breastmilk and/or breastmilk substitutes to eating ~~the normal~~ family diet.*

4. SUITABLE RAW MATERIALS AND INGREDIENTS

4.1 Basic R*aw Materials and* Ingredients

The following raw materials, most of which are locally available, are suitable ingredients for the production of ~~f~~Formulated ~~supplementary~~ ~~c~~*Complementary* ~~f~~Foods for older infants and young children under the specified conditions given below:

4.1.1 Cereals

4.1.1.1 All milled cereals suitable for human consumption may be used provided that they are processed in such a way as to reduce the fibre content, when necessary, and *to decrease and, if possible*, to eliminate *anti-*

[1] The Guidelines on Formulated Supplementary Foods for Older Infants and Young Children were adopted by the Codex Alimentarius Commission at its 19th Session in 1991.

nutrients such as phytates, tannins or other phenolic materials, *lectins* and *trypsin and chymotrypsin inhibitors* which can lower the protein *quality and* digestibility*, amino acid bioavailability~~, protein quality~~ and mineral absorption.*

4.1.1.2 Besides carbohydrates (mainly consisting of starch) cereals contain a significant quantity of protein (8-12%) *but are limiting~~s~~ in the amino acid lysine*. ~~Whereas rice has a satisfactory essential amino acid composition other cereals are as a rule limiting [limited**]** in lysine.~~ *Combining cereals with ~~other~~ legumes and/or pulses, which are higher in lysine, can compensate for the limiting level in cereals ~~amino acids~~.*

4.1.2 ***Legumes and*** **Pulses**

4.1.2.1 *Legumes and* ~~P~~pulses, including chick peas, lentils, peas, cowpeas, mungo beans, green gram ~~and~~ kidney beans ~~,~~ *and soya contain at least* ~~are a source of appropriate proteins (~~20 ~~– 24 [**35**]~~% ~~)~~ *protein*

4.1.2.2 On the whole, *legumes and* pulses ~~have a high content of lysine. They~~ are ~~, however,~~ deficient in L-methionine. Depending on the nature of the other ingredients in the formulation, the addition of L-methionine might be desirable in order to improve the nutritional value of the product.

4.1.2.3 *Legumes and* ~~P~~ *p*ulses have to be appropriately processed to *reduce* ~~eliminate~~, as *much* ~~far~~ as possible, the anti-nutritional factors normally present such as phytates, lectins (haemagglutenins), ~~and~~ trypsin and chymotrypsin inhibitors~~: [~~and *phytoestrogens]*;

- Lectins can be *reduced* ~~destroyed~~ by *moist* heat treatment;
- Trypsin inhibitor activity may be reduced to acceptable levels by ~~*soaking and*~~ heating to high temperatures or by prolonged boiling.
- *Phytate can be reduced enzymatically or by soaking or fermentation*.
- *[Phytoestrogens can be reduced by fermentation*.]

4.1.2.4 Field beans *or faba beans* (***Vicia faba L.***) ~~while having a very good nutritional quality and being a high yield crop,~~ should not be used in the formulation of complementary ~~supplementary~~ food for older infants and young children because of the danger of favism. Heat treatment does not completely inactivate the toxic *components* ~~principles~~ (vicine and co-vicine).

4.1.3 **Oil Seed Flours and Oil Seed Protein Products**

4.1.3.1 Flours, protein concentrates and protein isolates of the following oil seeds are acceptable if manufactured to appropriate specifications[2,3,4,5] *which assure sufficient reduction of anti-nutritional factors and undesirable toxic substances such as trypsin and chymotrypsin inhibitors and gossypol*:

Soya beans: dehulled flour, (full fat and defatted) *protein* concentrate, *protein* isolate

Groundnuts: ~~defatted flour~~ paste, *protein* isolate ~~(full fat and defatted)~~

Sesame seed: whole ground and defatted flour

Cottonseed: defatted flour

Sunflower seed: defatted flour, full fat

~~Canola~~ *Low erucic acid rapeseed: full fat flour*

4.1.3.2 *Defatted* oil seed flours and protein *isolates* ~~products~~ are ~~a rich~~ *good* source*s* of protein (50-95%). **[**~~They could provide the main source of proteins in Formulated *Complementary* Supplementary Foods~~] ~~for Older Infants and Young Children~~.

[2] The following Guidelines were elaborated by the FAO/WHO/UNICEF Protein and Energy Advisory Group:
PAG Guidelines No 2: Preparation of Food Quality Ground Flour
PAG Guidelines No 4: Preparation of Edible Cotton Seed Protein Concentrates
PAG Guidelines No 5: Guideline for Heat Processed Soy Grits and Flours
[3] Codex standard for Vegetable Protein Products (Codex STAN 174-1989)
[4] Codex standard for Soy Protein Products (Codex STAN 175-1989)
[5] Codex standard for Wheat Protein (Codex STAN 163-1987)

4.1.4 ***Animal Source Foods*** ~~**Fish Meals and Fish Protein Concentrates**~~

4.1.4.1 *Animal source foods such as meat, fish, poultry, milk and eggs are nutrient dense and good sources of high quality proteins and micronutrients and their incorporation in Formulated Complementary Foods as technologically feasible is encouraged.* ~~*should be promoted during the complementary feeding period*~~

4.1.4.2 *Milk and most milk products are* ~~*nutrient dense and good*~~ *sources of high quality proteins and* ~~*other*~~ *micronutrients. They are beneficial to growth and development and can be added to Formulated* ~~*c*~~*Complementary* ~~*f*~~*Foods.* ***[****Whey proteins are a readily available source of high quality protein* ~~*with a high bioavailability*~~ *which can be used to improve the protein level of* ~~*f*~~*Formulated* ~~*c*~~*Complementary* ~~*f*~~*Foods****]***

4.1.4.3 ~~Fish Meals and Fish Protein Concentrates~~ Fish protein concentrates have a protein content of 70-80%. **[**The protein is of high *nutritional* quality and high in lysine**]** ~~content~~. *If produced under appropriate conditions, fish protein concentrates are acceptable ingredients for Formulated Complementary Foods.*

~~4.1.4.2.1 Food quality meals from c~~*E*~~dible fish species are good sources of proteins and micronutrients.~~ and edible fish protein concentrates are acceptable if produced under appropriate ~~conditions[6]. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour shelf life.~~ ***(Last sentence moved down as part of section 4.1.5)***

~~4.1.4.2.2 Fish protein concentrates have a protein content of 70-80%. The protein is of high nutritional quality and high in lysine content. If produced under appropriate conditions, fish protein concentrates are acceptable ingredients for Formulated Complementary Foods.~~

~~*4.1.4.3 Milk and most milk products are nutrient dense and good sources of high quality proteins and other micronutrients. They are beneficial to growth and development and can be added to Formulated cComplementary fFoods. Whey proteins are a readily available source of high quality protein with a high bioavailability which can be used to improve the protein level of fFormulated cComplementary fFoods* ***(moved to section 4.1.4.2)***~~

4.1.5 **Fats and Oils**

4.1.5.1 Fats and oils *can* s~~hould~~ be *incorporated in adequate quantities as technologically feasible* ~~added to the preparation if possible~~ for the purpose of increasing the energy density of the product. *Care must be taken to avoid 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.*

~~4.1.5.2 The minimum requirements for essential fatty acids should be met.~~ ***(moved down as part of section 6.4.2)***

4.1.5.2 ~~*4.1.5.3*~~ *Partially hydrogenated fats [and oils]* ~~*containing (trans fatty) acids*~~ *should not be used in* ~~*f*~~ *Formulated* ~~*c*~~*Complementary* ~~*f*~~*Foods*[6] ~~]for older infants and young children (Codex STAN 074-1981, Rev. 1-2006)~~

~~4.2 Other Ingredients~~

~~The following ingredients may used to improve the nutritional quality and /or acceptability of the food provided that they readily available:~~

~~*4.1.6 4.1.5.4* **Milk and/or milk products**~~

~~*4.1.6.1 Milk and most milk products are nutrient dense and good sources of high quality proteins and other micronutrients. They are beneficial to growth and development and can be added to Formulated cComplementary fFoods. Whey proteins are a readily available source of high quality protein with a high bioavailability which can be used to improve the protein level of fFormulated cComplementary fFoods* ***(Moved up to 4.1.4.3)***~~

[6] Codex STAN 074-1981, REV. 1-2006

4.2 Other Ingredients

The following ~~ingredients~~ may be used to improve the nutritional quality and/or acceptability of the *Formulated Complementary* Foods ~~food~~ provided that they are readily available~~:~~ *and have been proven to be suitable and safe for their intended purpose.*

~~4.2.1 **Milk and/or milk products** **(*Has been moved up*)~~

~~*4.2.1 Animal Source Foods*~~

~~*Animal source foods such as meat, fish, poultry and eggs are nutrient dense and good sources of high quality proteins and micronutrients and should be promoted during the complementary feeding period.*~~ **(*Has been moved up*)**

4.2.1 ~~2.~~ **Digestible carbohydrates ~~including sugars~~**

4.2.1.1 Energy density *of Formulated Complementary Foods can* ~~should preferably~~ be increased by the addition of ~~fat and/or~~ digestible carbohydrates. ~~, *including sugars*. If [sugars[5]] nutritive sweeteners are used, they should be used *sparingly, taking into account the reccommendation in the Global Strategy on Diet, Physical Activity and Health to limit intake of free sugars*[4]. in moderation *provide less than 10% of the total energy of the product*[7].~~

(*Part of this text has been moved to section 6.5 under carbohydrates as it appears to fit better in that section*)

4.2.2 ***Food additives and*** **Flavours**

4.2.2.1 ~~4.3.2~~ *Food additives and flavours listed in the Codex Standard for Processed Cereal-Based Foods for Infants and Young Children (Codex STAN 074-1981, REV 1-2006) may be used in Formulated Complementary Foods to the maximum limits given in that Standard.* ~~**Flavours**: *Ethylvanillin and vanillin (maximum 7 mg/100g RTU), natural fruit and vanilla extract*, vanilla and/or traditional flavours *may be used* provided they have been evaluated for their safety in use.~~

~~4.3.2 4.2.4 *Food additives allowed for use in Codex STAN 074-1981, Rev. 1-2006 are permitted for use in fFormulated Complementary fFoods*.~~

~~4.2.53 **Other ingredients of food quality**:~~

~~4.2.53.1 *Other ingredients of food quality may be used in Formulated Complementary Foods* provided they have been proven to be suitable *and safe* for their intended purpose.~~

5.0 TECHNOLOGIES FOR EFFECTS OF PROCESSING

5.1 Preliminary Treatment of Raw Materials

Cereals, pulses and oilseeds should first be treated to obtain wholesome and clean raw materials of good quality. Such treatments include, *but are not limited to*:

5.1.1 **Cleaning or washing**: to eliminate dirt, damaged grains, foreign grains and noxious seeds, insects and insect excreta and any adhering material.

5.1.2 **Dehulling**: when necessary, pulses, oilseeds and certain cereals such as oats, barley, sorghum, ~~*and*~~ millet and teff should be dehulled as completely as is feasible to reduce the ~~[dietary]~~ ~~crude~~ fibre content to acceptable levels and to *decrease, and if possible*, ~~and~~ to eliminate *phytates*, tannins and other phenolic materials, *trypsin and chymotrypsin inhibitors* which can lower the protein digestibility *and amino acid bioavailability and mineral absorption*.

5.1.3 **Degermination**

5.1.3.1 Where necessary and appropriate, degermination of wheat, corn, soy and other crops should be considered in order to reduce *the* phytate~~s~~ content.

5.2 Milling ~~ed Products~~

5.2.1 Milling or grinding of suitable raw materials should be carried out in such a way as to minimize the loss of nutritional value and to avoid undesirable changes in the technological properties of the ingredients.

5.2.2 Dry raw materials may be milled together, if technologically feasible, or mixed after milling or grinding.

5.2.3 Formulations containing milled cereals, legumes, pulses and/or oilseeds that have not been otherwise processed ~~without further processing~~ require prolonged boiling ~~during the preparation of the feed~~ to gelatinize the starch portions and/or eliminate anti-nutritional factors present in *legumes and* pulses. Boiling improves the digestibility and absorption of nutrients. ~~and sterilizes the feed.~~

5.2.4 The bulkiness of foods ~~feeds~~ from food formulations containing dry ingredients obtained by milling of the raw materials can be reduced by adding, during the formulation, adequate amounts of enzymes such as alpha-amylase which, during the slow heating to boiling, predigest partially the starch and reduce the amount of water needed for the preparation of the food ~~feed~~.

5.3 Toasting

5.3.1 Toasting (dry heating) enhances the flavour and the taste of the food through dextrinization of starch. It also improves digestibility and contributes to reducing the bulkiness of the formulated food. Moreover, it destroys micro-organisms and insects and reduces enzyme activity, thus improving keeping qualities.

5.3.2 Protein damage due to the Maillard reaction may occur in the presence of reducing carbohydrates. The toasting process should therefore be carefully controlled.

5.3.3 Pulses as well as oilseeds such as soya beans, groundnuts and sesame seeds can be toasted as whole grains directly or after soaking. ~~Soaking results in puffed grains with a light texture.~~

5.3.4 Toasted raw materials can be milled or ground for use as ingredients.

5.4 Sprouting ~~and~~ *, Malting and Fermentation*

5.4.1 Cereals and pulses can be induced to germinate by soaking or humidifying. It is necessary, however, to ensure that growth of mycotoxin producing microorganisms does not occur. The action of natural amylases contained in the grains results in the predigestion of the starchy portion of the grain (dextrinization) thus reducing the bulk of the food when prepared for feeding and, ultimately, increasing the nutrient density of the food. Sprouting**,** *malting and fermentation can induce ~~phytates~~ hydrolysis of phytates and decrease its inhibitory effect on mineral absorption, and may improve B vitamin content.*

5.4.2 During the ~~process~~ *germination process*, the seed coat of the grain splits and can be removed by washing. The malted raw material is milled or ground after drying.

5.5 Advanced Processing Technologies

5.5.1 **Extrusion Cooking**

5.5.1.1 The mix of milled or ground basic ingredients (cereals, pulses, oilseed flours) may be further processed by extrusion-cooking. Extrusion cooking may *decrease* ~~affect~~ available *L*-lysine, sulphur-containing amino acids, *L*-arginine, ~~and~~ *L*-tryptophan *and vitamins*. The process should therefore be carefully controlled. The extruded product, after drying if necessary, is milled or ground to the desired particle size.

5.5.1.2 The effects of this technology are:

- gelatinization of the starchy portion of the mixture with minimal quantities of water;
- inactivation of lectins and ~~simultaneous~~ reduction of trypsin inhibitor activity;
- a reduction in the quantities of water needed for preparation of the ~~feed~~ *food.*
- *flavour development*

5.5.2 **Enzymatic Predigestion**

5.5.2.1 ~~Under~~ *With* this process the milled or ground basic ingredients (cereals, pulses, oilseed flours) *can be* ~~are~~ *processed in the presence of water and appropriate enzymes* ~~slowly heated~~ under continuous stirring until the mixture acquires the desired fluidity. *In the case of use of amylase ~~enzymes~~,* ~~S~~ 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*.

5.5.2.2 The predigested product *may have* ~~has~~ improved organoleptic characteristics, higher digestibility, good solubility, ~~and~~ requires less water for the preparation of the *food* ~~feed.~~ *,and hence higher nutrient density*

6. ~~FORMULATION~~ *NUTRITIONAL QUALITY*

6.1 ~~Nutritional Aspects (General)~~ *General Aspects*

~~6.1.1 In accordance with the purpose of these guidelines and the definition of "Formulated Supplementary Complementary **[complementary supplemented]** Foods for Older Infants and Young Children", the product is intended to supply additional energy and nutrients to **the local diets** staple foods used for the feeding of older infants and young children. The following sections might not be applicable under all conditions prevailing in different countries and appropriate modifications might have to be made for adapting them to specific conditions.~~

6.1.1 ~~6.1.3~~ The selection of *raw materials and* ingredients for the formulation of Formulated *Complementary* ~~Supplementary~~ Foods for Older Infants and Young Children should be made having regard to the provisions in Sections 4 *and 5* ~~through 6.1.2 above~~ and taking into account the following aspects:

- nutrient content of the local diet ~~(including breast milk) staple food~~;
- *nutrient content of breast milk and breastmilk substitutes*;
- dietary habits;
- other socio-economic aspects as determined by the national authorities dealing with nutrition;
- availability and costs of raw materials and ~~other~~ ingredients.

6.1.3 Ten to fifty ~~One hundred~~ grammes of the product, when prepared according to the instructions, is considered a reasonable quantity which an older infant or young child *fed breast milk or breast milk substitute* can ingest easily in two or more feedings *per day*. *This range provides an allowance for the various types of ƒFomulated єComplementary ƒFoods. The lower part of the range apply 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, cereal-based products)*

~~6.1.3 The selection of ingredients for the formulation of Formulated *Complementary* Supplementary Foods for Older Infants and Young Children should be made having regard to the provisions in Sections 4 through 6.1.2 above and taking into account the following aspects:~~

~~* nutrient content of the local diet (including breast milk) staple food;~~

~~* *nutrient content of breast milk//breast milk substitutes*~~

~~* dietary habits;~~

~~* other socio-economic aspects as determined by the national authorities dealing with nutrition;~~

~~* availability and costs of raw materials and other ingredients.~~

(***Moved up to become now 6.1.1***)

~~6.1.4 In cases where older infants and young children are given specific vitamins and/or minerals through maternal and child health centres or other health agencies, the addition of these vitamins and/or minerals to complementary supplementary foods may be unnecessary, provided that distribution of the complementary supplementary [complementary supplemented] foods is carefully limited to those receiving the vitamins and/or minerals.~~

~~***6.1.4*** *Care must be taken to ensure that the total micronutrient intake from the formulated complementary food, local diet (including breast milk and/or breast milk substitutes), and other sources do not regularly*~~

~~*exceed relevant upper levels of micronutrient intake for older infants and young children.*~~ (***Moved down to become now 6.6.5***)

6.1.2 *All processing should be carried out in a manner that maintains ~~keeps~~ protein quality and minimizes loss of micronutrients and maintains overall nutritive value.*

6.2 Energy

6.2.1 The energy density of a mixture of milled cereals and pulses and defatted oilseed meals and flours *on dry weight basis* is relatively low

6.2.2 The energy density of the food can be increased *during manufacture* by~~:~~

(a) the ~~*preferable*~~ addition of *energy-containing ingredients (i.e.*, fats and oils *and /or ~~during the manufacture by;~~*, ~~and/or~~

~~(b) *the possible addition of* digestible carbohydrates) including , in moderation, sugars;~~ and/or,

~~(c)~~ processing the basic *raw materials and* ingredients as indicated in Section 5.

6.2.3 The energy density ~~One hundred grammes~~ of the *Formulated Complementary ~~f~~ Food* should *be* ~~provide~~ at least *4 kcal per gram on dry weight basis*. ~~400 kcal.~~

6.3 Proteins

6.3.1 *Mixtures of ~~C~~* cereals, legumes*, pulses* and/or oilseed flours, ~~alone or preferably mixed,~~ can constitute an appropriate source of proteins, provided ~~they are prepared in such a way~~ that ~~in the finished product~~ the proteins in the *Formulated Complementary Food* ~~mixture~~ 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.*

6.3.2 The Protein Digestibility Corrected Amino Acid Score (PDCAAS)[7,8,9]~~]~~ ~~amino-acid score~~[4] ~~(previously called the chemical score) corrected in accordance with the true digestibility of the crude proteins,~~ should not be less than ~~*0.70.*~~ 70 per cent of that of casein. ~~Higher values should be required if calculation of the score was based not, as is usually the case, on the most limiting amino acid, but on two or more key amino acids such as lysine, methionine, cystine, threonine and tryptophan.~~

6.3.3 If, for technical reasons, the PDCAAS ~~amino acid score and the~~ *digestibility* of a protein cannot be determined, the protein quality should be measured by biological assays. Alternatively, the protein quality may be *calculated* ~~computed~~ from published data on essential amino acid patterns of dietary proteins and their digestibility.

6.3.4 The addition of methionine, lysine, tryptophan or other limiting amino acids, solely in the L-form ~~(except for DL-methionine, which may be used in foods for children over 12 months of age)~~ 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).

6.3.5 Taking into account the preceding considerations, *the energy from protein*[10] ~~**content**~~ *should not be less than 10% of the total energy from the product*[11,12] ~~. be in the order of 15 g per 100 g of the food on a dry matter basis~~[6] *and should not exceed 15%*[13]

6.4 Fat

6.4.1 Incorporation of ~~adequate quantities of~~ fats and/or oils *in Formulated Complementary Foods serves* ~~,~~ ~~as technologically feasible, is recommended in order~~ to increase the energy density~~,~~ *and the amount of*

[7] PDCAAS (%)= mg of limiting amino acid in 1 gram of test protein X ~~faecal~~ true digestibility of test protein *X 100*
mg of limiting amino acid in 1 gram of reference protein

[8] The limiting amino acid is the essential amino present in the lowest proportion as compared with the quantity of this amino acid reference protein

[9] WHO Protein and amino acid requirements in Human Nutrition, Geneva; WHO 2007

[10] Conversion factor based on Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985)

[11] Complementary feeding of young children in developing countries: review of current scientific knowledge, Geneva, WHO 1998

[12] FAO/WHO Expert Consultation on Fats and fatty acids in human nutrition. Geneva 2008

[13] Michaelsen KF et al. 2009. Food and Nutr Bull 30:343-404

essential fatty acids ~~and~~ as well as reduce total volume of the food consumed. ~~of the product. A level of between 20% and 40% of energy derived from fat would be desirable.~~ *At least 30% of energy derived from fat*[10] *is ~~would be~~ desirable*[11]. ~~This corresponds to between about 10 g and 25 g of fats and/or oils in 100 g of the food.~~

6.4.2 The level of linoleic acid (in the form of glycerides) should not be less than ~~300~~ *333* mg per 100 kcal or ~~1.4~~ *1.6* g per 100 g of *dry* product[12] *and the fat or oil used in the production of Formulated Complementary Foods should ensure a ratio between linoleic acid and alpha-linolenic acid ~~should be~~ of between 5:1 and 15:1.*

(Alternative wording for 6.4.2 suggested below)

[6.4.2 The use of edible oils containing polyunsaturated fatty acids, including omega-3 fatty acids and in particular docosahexaenoic acid, should be considered. The levels should conform to WHO/FAO recommendations (FAO/WHO Expert consultation on Fats and fatty acids in human nutrition, Geneva[12]*]*

~~6.4.3 Where it is not feasible to include all of the desired fats and/or oils in the formulation of the food, the instructions for use on the label should recommend the addition of a specified quantity of fats and oils with an appropriate essential fatty acid ratio during the preparation of the **feed food.** ***(Moved to labeling)***~~

6.5 Carbohydrates

6.5.1 Starch is likely to be a major constituent of many *Formulated ~~c~~Complementary* ~~supplementary f~~*Foods* ~~for older infants and young children~~. 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 sweetners are used, they should be used sparingly, ~~[taking into account the recommendation in the Global Strategy on Diet, Physical Activity and health to limit intake of free sugar~~*[14]*~~]~~*

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.

~~6.5.2~~ Increasing the intake of dietary fibres[14~~11~~] *increases* ~~enhances~~ stool bulk*, may cause flatulence and decrease appetite.* ~~They also may~~ *Fibre load also can reduce the energy density of Formulated Complementary Foods. They also may* affect the efficiency of absorption of *important* ~~various~~ nutrients ~~of significance~~ *from* ~~in~~ diets with ~~a~~ marginal nutrient content*s.* ~~so~~ **[***T*he dietary fibre content of the ~~f~~*Formulated ~~c~~Complementary ~~f~~Food* should *therefore* be reduced to a level not exceeding 5 g per 100 g *on a dry weight basis.***]**

6.6 Vitamins and Minerals

6.6.1 Setting levels for the addition of vitamins and ninerals

6.6.1.1 ~~2~~ The *decision to add* ~~addition of~~ vitamins and minerals *to a Formulated Complementary Food* should take into account local ~~nutrition and health~~ conditions *including the nutrient contribution to the diet from local foods, vitamin and mineral ~~supplements~~ 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 Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987).*

6.6.1.2 If the dietary intake data for the target population is available it can be used to determine appropriate levels for the addition of vitamins and/or mineral to ensure a low prevalence of inadequate and excessive nutrient intakes using the WHO intake monitoring assessment planning program (IMAPP).

6.6.1.3 ~~2 6.6.4~~ *If the dietary intake data for the target population is not available, the vitamins and minerals* listed *in* ~~T~~*t*he Table in the Annex to these Guidelines ~~contains the reference daily *nutrient intakes (RNIs)* requirements *Estimated Average requirements* for the vitamins and minerals that are most frequently deficient in the diets of *are those for which Individual Nutrient Levels$_{98}$ (INL$_{98}$) have been established for* older infants and young children. *These values provide* can be used as a reference for the selection of~~

[14] *Definition of Dietary fiber given in the* Codex Guidelines on Nutrition Labelling (CAC/GL 2-1885)

particular vitamins and minerals and their amounts for addition to a Formulated Complementary Food. ~~It is important to keep in mind that the Table is simply a guideline to emphasize the nutrients to be considered in the development of a *formulated complementary* supplementary food.~~

6.6.2 National authorities should [are encouraged to] ~~to~~ ensure that the total micronutrient intake from the ~~f~~Formulated ~~c~~Complementary ~~f~~Foods, local diet, (including breast milk and/or breast milk substitutes)~~,~~ and other sources do not regularly exceed recommended ~~relevant~~ upper levels of micronutrient intake for older infants and young children.

6.6.3 Selecting vitamins and/or minerals for fortification

6.6.3.*1* ~~2~~ When establishing the specifications for the premix of vitamin compounds and mineral salts, the vitamin and mineral content *and presence of antinutritive substances in* ~~of~~ the other ingredients used in the formulation of the food should be taken into account.

6.6.*3.2* ~~4 3~~ Vitamins and/or minerals should be selected from the Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979-*Rev 2008*).

[*6.6.3.3 The choice of vitamin and/or mineral compound should take into account its relative bioavailability within the food vehicle, the effect on the sensory properties of the food vehicle, its cost, and its stability in the packaged food vehicle under normal storage conditions. The FAO/WHO Guidelines on Fortification with Micronutrients provides specific guidelines in this area****]***[15]

~~6.6.4 The Table in the Annex to these Guidelines contains the reference daily *nutrient intakes (RNIs)* requirements *Estimated Average requirements* for the vitamins and minerals that are most frequently deficient in the diets of *for* older infants and young children. It is important to keep in mind that the Table is simply a guideline to emphasize the nutrients to be considered in the development of a *fo*~~

~~*rmulated complementary* supplementary food~~. ***(Moved up as 6.6.2)***

~~***6.6*.5 6.*1.4*** *Care must be taken National authorities should to ensure that the total micronutrient intake from the fFormulated cComplementary fFoods, local diet (including breast milk and/or breast milk substitutes), and other sources do not regularly exceed recommended relevant upper levels of micronutrient intake for older infants and young children.*~~

~~***6.7 Quality***~~

~~***6.7.1*** *All processing should be carried out in a manner that maintains keeps protein quality and minimizes loss of micronutrients and maintains overall nutritive value. (**Moved to section 6.1.2)***~~

7. HYGIENE

It is recommended that Formulated *Complementary* ~~Supplementary~~ Foods for Older Infants and Young Children comply with the following mandatory hygiene requirements:

7.1 To the extent possible in good manufacturing practice, food products shall be free from objectionable matter.

7.2 When tested by appropriate methods of sampling and examination, the product:

(a) shall be free from pathogenic microorganisms;

(b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and

(c) shall not contain any other poisonous or deleterious substances in amounts which may represent a hazard to health.

7.3 The product shall be prepared, packed and held under sanitary conditions and should comply with ~~the~~ *relevant codex texts*[16]. ~~Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21–1979).~~

[15] WHO/FAO 2006. Guidelines on food fortification with micronutrients

[16] Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997); The Recommended International Code of Practice – General Principles of Food Hygiene ~~for Foods for Infants and Children~~ (CAC/RCP 1-1969); Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004)

8. PACKAGING

8.1 It is recommended that Formulated *Complementary* ~~Supplementary~~ Foods for Older Infants and Young Children be packed in containers which will safeguard the hygienic and other qualities of *the* food.

8.2 The containers, including packaging material, shall be made only of materials which are safe and suitable for their intended uses.

9. LABELLING

9.1 It is recommended that the labeling of Formulated *Complementary* ~~Supplementary~~ Foods

for Older Infants and Young Children be in accordance with the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985)[7] ~~.~~ ,~~*and*~~ *Guidelines for the Use of Nutrition and Health Claims (CAC/GL 23-1997. ~~Nutrition claims may be permitted under national legislation provided that they have been demonstrated in rigorous studies with adequate scientific standards~~ and Guidelines for Nutrition labeling (CAC/GL2-1985 revision 2009)*

or ***(Alternative text for 9.1 suggested below)***

[9.1 *The requirement of the Codex General Standard for the Labeling of and Claims for Prepackaged Foods for Special Dietary uses (CODEX STAN 146-1985), the Guidelines on Nutrition Labelling (CAC/GL 2-1985) and the Guidelines for the Use of Nutrition and Health Claims (CAC/GL 23-1997) apply to the labeling of Formulated Complementary Foods. Where appropriate, relevant CODEX Standards, such as the CODEX Standard for processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 074-1981, Rev 1-2006) and the CODEX Standard for the labeling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) should be taken into consideration.**]**

9.2 The following mandatory provisions should apply:

9.2.1 The Name of the Food

9.2.1.1 The name of the food to be declared on the label shall indicate that the food is a ~~*f*~~*Formulated* ~~*c*~~*Complementary* ~~supplementary~~ ~~*f*~~*Food*, ~~as appropriate,~~ for older infants and young children ~~*at risk of malnutrition*~~. The appropriate description should be in accordance with national legislation.

9.2.1.2 The following information shall appear in close proximity to the name of the food:

(a) the major sources of protein;

(b) a statement that the food ~~may be administered as a food supplement during the weaning complementary feeding period but not before **the** 6 th months of age.~~ *should be given* when nutritional requirements *of older infants and young children* are not *met* by locally available foods *during the complementary feeding period***.**

(c) a statement that the food should not be fed to infants under 6 months of age.

(d) a statement that Formulated Complementary Foods are to be consumed in addition to family foods and breast milk.

[*(e) Any statement required by CODEX Standards or related text or required by the laws of the country in which the food is distributed.****]***

9.2.2 List of Ingredients

The list of ingredients shall be declared in accordance with Section 4.2 of the General Standard *for the Labeling of Prepackaged Foods (Codex STAN 1-1985)*.

9.2.3 Declaration of Nutritive Value

The declaration of energy and nutrients on the label or in labelling shall contain the following information expressed per 100 grammes of the *Formulated Complementary* ~~f~~*F*ood as sold *or otherwise distributed* ~~*made available*~~ **~~in the final product~~ [**as well as per *feeding* ~~**specified quantity**~~ of the food *ready for consumption:* ~~**. as suggested for consumption per serving:**~~**]**

(a) ~~the amount of~~ energy *value*, expressed in kilocalories and kilojoules;

(b) the amounts of protein, carbohydrates and fat, expressed in grammes ~~[and the amount of linoleic and alpha-linolenic acid]~~,;

(c) in addition to any other nutritional information required by national legislation, [the total quantity *per feeding of* ~~in~~ the *Formulated Complementary ~~f~~Food* ~~final product~~ *ready for consumption]* of each vitamin and mineral added in accordance with Section 6.6 expressed in metric units

(Alternative text for 9.2.3 suggested below)

[*9.2.3 The mandatory declaration of the energy and nutrients on the label should be in compliance with the Guidelines on Nutrition Labelling (CAC/GL 2-1985)***]**

9.2.4 ~~**Information for Utilization**~~ ***Instruction for use***

9.2.4.1 Directions as to the preparation and use of the food shall be given; preferably accompanied by pictorial presentations.

9.2.4.2 *The suggested number of feedings per day should be indicated.*

9.2.4.3 In the case that addition of water is needed, the directions for the preparation shall include a precise statement that:

(a) where the food contains non-heat-processed basic ingredients, the food must be adequately boiled in a prescribed amount of water;

(b) where the food contains heat-processed basic ingredients:

(i) the food requires boiling, or (ii) can be mixed with ~~cold or warm~~ boiled water *that has been cooled* ~~, as appropriate~~.

9.2.4.4 *For Formulated Complementary* ~~F~~*F*oods *to* which ~~have been formulated with the intent that~~ fats, sugars or other digestible carbohydrates *should be* ~~are~~ added during preparation, *the instructions for use shall identify appropriate sources and* ~~shall bear an~~ *indicate* ~~*ion* of~~ the amounts *of the ingredients to be added.* ~~which are required to achieve the desired nutrient density of the food.~~ ~~*i*~~*In such situations, fats and oils with an appropriate essential fatty acid ratio should be recommended***.**

9.2.4.5 Directions for use shall include a statement that only *an* ~~the~~ amount of food sufficient for one *feeding occasion* ~~meal~~ should be prepared at one time. ~~*Leftovers after the child has consumed the f*~~*Foods not consumed during the feeding occasion should be discarded.*

ANNEX

TABLE

The *reference INL_{98} values* ~~vitamins and minerals~~ listed in the Table ~~include those for which *nutrient levels have been established for* deficiency is most frequently found in older infants and young children and *provide a guide for selection and amounts of vitamins and minerals* should be considered in the formulation of~~ *to be added to* a *Formulated Complementary Food.* ~~supplementary food~~. ~~Local conditions including the nutrient contribution to the diet from **the** local **diets foods** staple foods of the area and the nutritional status of the target population as well as national legislation should be taken into account in determining the nutrients to be added. When a food is enriched **fortified** supplemented with one or more of these **nutrients vitamins and minerals**,~~ ~~t~~The *suggested* total ~~**amount**~~ *quantity* of ~~**the**~~ *each of these* ~~**added**~~ vitamins and/or minerals contained *in a* ~~**per**~~ *daily ration* ~~in 100 g~~ of the *fFormulated Complementary Food* ~~**on a dry matter basis** should be~~ *is* at least ~~50~~ 70% *INL_{98}* ~~2/3 of the reference nutrient intake. daily requirements.~~

VITAMINS AND MINERALS	**REFERENCE[17] NUTRIENT INTAKE (RNI) or Individual Nutrient Levels$_{98}$ (INL_{98})**	**ESTIMATED[18] AVERAGE REQUIREMENT (EAR; 100%)**	**[3]70% of RNI[19] (As calculated by Australia)**
Vitamin A µg retinol equivalent	400	286	280
Vitamin D[20] 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

[17] RNI or INL_{98} from FAO/WHO Vitamins and Mineral requirements in Human Nutrition. 2nd Edition. FAO/WHO 2004 (for all nutrients except copper, manganese and phosphorus)
[18] Estimated Average Requirement (calculated values) based on FAO/WHO Recommended Nutrient Intakes. FAO/WHO Guidelines on Food Fortification with Micronutrients (WHO and FAO, 2006)
[19] These values were calculated by EWG Australia delegation, 70% of the RNI (INL_{98})
[20] Vitamin D should be added if there is inadequate exposure to sunlight

VITAMINS AND MINERALS	**REFERENCE[21] NUTRIENT INTAKE (RNI) or Individual Nutrient Levels$_{98}$ (INL$_{98}$)**	**ESTIMATED[22] AVERAGE REQUIREMENT (EAR; 100%)**	**[3]70% of RNI[23] (As calculated by Australia)**
Vitamin B_{12} µg	0.9	0.7	0.63
Calcium mg	500	417	350
Iron mg[24]	11.6, 5.8, 3.9	11.6, 5.8, 3.9	8.1,4.1, 3.4
Zinc mg[25]	8.3, 4.1, 2.4	6.9, 3.4, 2.0	5.8
Iodine µg	90	64	63
Copper mg[26]	0.34	~~0.56~~ 0.34	
Selenium µg	17	14	11.9
Vitamin K ~~mg~~ µg	15	15	10.5
Biotin µg[24]	8	8	5.6
Pantothenic acid mg[24]	2	2	
Magnesium mg[24]	60	60	
Manganese mg [27]	1.2	1.2	
Phosphorus mg[25]	460	460	

[21] RNI or INL$_{98}$ from FAO/WHO Vitamins and Mineral requirements in Human Nutrition. 2nd Edition. FAO/WHO 2004 (for all nutrients except copper, manganese and phosphorus)
[22] Estimated Average Requirement (calculated values) based on FAO/WHO Recommended Nutrient Intakes. FAO/WHO Guidelines on Food Fortification with Micronutrients (WHO and FAO, 2006)
[23] These values were calculated by EWG Australia delegation, 70% of the RNI (INL$_{98}$)
[24] Because of skewed distribution of iron requirements for young children, the corresponding 100% RNI values are given for 5%, 10 % and 15% respectively, dietary iron bioavailability
[25] Zinc 100% EAR for low, medium and high; dietary zinc bioavailability
[26] Values are 100% Recommended Nutrient Intakes
[27] Values are Dietary Reference Intakes. Institute of Medicine, 2002/2005 (Source for Copper, Manganese and Phosphorus).

APPENDIX 1

LIST OF MEMBERS OF THE ELECTRONIC WORKING GROUP ON CCNFSDU

AUSTRALIA

Janine Lewis
P. O Box 7186, Canberra BC ACT 2610,
AUSTRALIA
Ph: +61 2 6271 2245
Janine.lewis@foodstandards.gov.au

Kate Slater
Codex International Standards
Export Standards Branch
Food Division, Biosecurity Services Group
Department of Agriculture, Fisheries and Forestry
Ph: +61 2 6272 4542 Fax: +61 2 6272 4389
kate.slater@daff.gov.au

ANTIGUA AND BARBUDA

Samantha Moitt
Member Country/Organization: Antigua and Barbuda
Emailaddress: samantha.moitt@gmail.com
Phone number(s): 764-3635 (cell) or 484 2761 (work)
Mailing address: Sutherlands Development
St. John's Antigua

BELGIUM

Ms. Sandra Tuijtelaars
International Dairy Federation (IDF)
Silver Building Boulevard Auguste Reyers 70
1030 Brussels, Belgium
Ph :+32 2 325 67 50
STuijtelaars@fil-idf.org

Mr. Xavier Lavigne
ISDI (International Special Dietary Foods Industries)
rue de l' Association 50, 1000 Brussels, Belgium
Ph**:** 00 32 2 209 11 43
xavierlavigne@isdi.org

Pascale De Gryse
Ph**:** 32 2 524 73 68
pascale.degryse@health.fgov.be

BOLIVIA

Catalina Fuentes
E-mail address: **catalina_csfz@hotmail.com;**
codex.bolivia@ibnorca.org
Phone number(s): 591 - 76540223
Mailing Address(s): Punto Contacto - Bolivia - Av. Busch # 1196 - Miraflores

BRAZIL

Elisabete Gonçalves Dutra
Member Country/Organization: National Health Surveillance Agency- Anvisa
SIA, Trecho 5, Área Especial 57 – Bloco D – Brasília – DF – CEP 71.205-050 - Brazil
Ph: (55) 61 34625333
elisabete.goncalves@anvisa.gov.br

Ana Claudia Marquim Firmo
Member Country/Organization: National Health Surveillance Agency- Anvisa
Mailing address: SIA, Trecho 5, Área Especial 57 – Bloco D – Brasília – DF – CEP 71.205-050 – Brazil
Ph: + (55) 61 34625332
Ana.firmo@anvisa.gov.br

CANADA

Ms. Isabelle Neiderer
International Dairy Federation (IDF)
Dairy Farmers of Canada
1801 McGill College Avenue, suite 700
H3E 2N4 Montreal, Canada
Tel: +1 514 284-1092
isabelle.neiderer@dfc-plc.ca

Christina Zehaluk MSc
Head, Special Purpose Foods
Health Canada

christina.zehaluk@hc-sc.gc.ca

CHINA

Han Junhua
7 Panjiayuan Nanli, Beijing 100021, China Ph: +0086-10-67791259.
hanjhua@163.com

DOMINICAN REPUBLIC

Dra. Matilde Vasquez
PCC-Dominican Republic.
Email: codexsespas@yahoo.com
Tel + 1 - 809-541-0382
Postal address: 10514

ESPGHAN

Prof. Walter Mihatsch
Diakonie-KlinikumDiakoniestraße 10
Schwäbisch Hall D-74523 Germany
Tel work: +49 791 753 4509
Mobile: +49 163 863 2380
walter.mihatsch@diaksha.de;
familie.mihatsch@web.de

EUROPEAN UNION

Ms Ariane Vander Stappen
Health and Consumers Directorate-General (SANCO)
B - 1049 Brussels
Tel.: ++32 - 2 - 295 21 58
ariane.vander-stappen@ec.europa.eu

Ms Helen Lee
Health and Consumers Directorate-General (SANCO)
B - 1049 Brussels
Tel.: ++32 - 2 - 299 86 68
helen.lee@ec.europa.eu / EU Codex Contact point (e-mail: **codex@ec.europa.eu).**

FRANCE

Prof. Dominique Turck
ESPGHAN
Département de Pédiatrie
Hôpital Jeanne de Flandre 2, avenue Oscar
Lambret59037 Lille cedex, France
Phone numbers: work: +33 3 20 44 68 85
- mobile: +33 6 08 18 48 15
dominique.turck@chru-lille.fr and
dominiqueturck@voila.fr

Guillaume Cousyn
Nutrition Division
Directorate for competition policy, consumer affairs and fraud control
Ministry of economy, finances and industry
Mail:guillaume.cousyn@dgccrf.finances.gouv.fr
Phone: + 33 1 44 97 33 19

DANONE

Mme Annie LOC'H,
E-mail address – annie.loch@danone.com
Phone number(s) – 33 (0)6 14 67 28 25
Mailing address – 15 rue du Helder 75099 Paris France

GERMANY

Dr. Hartmut Waldner
Bundesministerium für Ernährung,
Landwirtschaft und Verbraucherschutz (BMELV)
(Federal Ministry of Food, Agriculture
and Consumer Protection)
Rochusstraße 1
53123 Bonn, Germany
Phone: +49 (0) 228 99529-4961
Fax: +49 (0) 228 99529-4965
E-Mail: 313@bmelv.bund.de

ILCA

Maryse Arendt
ICLA International Location Consultant Caliber Association
Maryse.arendt@liewensufank.lu

JAPAN

Dr Eiji HINOSHITA
Office of International Food Safety, Department of Food
Safety, Ministry of Health, Labour and Welfare
E-mail: codexj@mhlw.go.jp
Telephone: +81 3 3595 2326
Mailing address: 1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8916, Japan

Dr Eiji HINOSHITA
Office of International Food Safety, Department of Food
Safety, Ministry of Health, Labour and Welfare
E-mail: codexj@mhlw.go.jp
Telephone: +81 3 3595 2326
Mailing address: 1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8916, Japan

Ms Reiko YONEKURA
Organization: Food Labeling Division, Consumer Affairs Agency
E-mail: g.foodlabeling@caa.go.jp
Telephone: +81 3 3507 9221
Mailing address: 2-11-1 Nagata-cyo, Chiyoda-ku, Tokyo 100-6178, Japan

Dr Yoshiko ISHIMI
Organization: National Institute of Health and Nutrition
E-mail: ishimi@nih.go.jp
Telephone: +81 3 3203 8063
Mailing address: 1-23-1 Toyama, Shinjuku-ku, Tokyo 162-8636, Japan

KENYA

Mr. Samuel Mbugua
Lecturer, Department of Human Nutrition, Egerton University - Kenya and the National Chairman, Nutrition and Foods for Special Dietary Foods Technical Committee
Email address:samwel.mbugua2@gmail.com

MALAYSIA

Ms Fatimah Sulong
PRINCIPAL Assistant director
FOOD safety and QUALITY Division
Ministry of Health Malaysia
62590 Putrajaya, Malaysia
Phone: +603 8885 0740
Email: fatimahsulong@moh.gov.my

NEW ZEALAND

Jenny Reid
Deputy Director (Science
MAF Food Safety
jenny.reid@maf.govt.nz
David Robert
Manager (Nutrition)
MAF Food Safety
P O Box 2835
68-86 Jervois Quay
Wellington 6011

David.roberts@maf.govt.nz

POLAND

Magdalena Kowalska
Member Country: Poland / Agricultural and Food Quality Inspection
E-mail address: mkowalska@ijhars.gov.pl
Phone number: +48 22623 29 04
Mailing address: 30 Wspolna Str. 00-930 Warsaw, Poland
Language: English

SWITZERLAND

Mrs Elisabeth Nellen-Regli
Consumer Protection Directorate
Food Safety Division
Swiss Federal Office of Public Health
Post Box, CH-3003 Bern, Switzerland
Tel. +41-(0)31 322 95 60 Fax +41 (0)31 322 95 74
E-mail: elisabeth.nellen@bag.admin.ch

THAILAND

Mr. Manat Larpphon,
Senior Standards Officer,
National Bureau of Agricultural commodity and Foods Standard, Ministry of Agriculture and Cooperatives, Thailand
Tel : +662 561 2277, Fax: +662 561 3357
manat@acfs.go.th; mlarpphon@yahoo.com
CC: Codex@acfs.go.th

URUGUAY

Nora Villalba
18 de Julio 1892 3er piso Anexo A 6 - Montevideo - Uruguay
Ph: 59824031725 o 16 interno 114 - movil 598 99698143 5
noravillalbacodex@gmail.com

UK

Ranulf Barman
Department of Health,7th Floor, Wellington House, 133-155 Waterloo Road, London, SE1 8UG, UK
Ph: +442079723233
Rakulf.barma@dh.gsi.gov.uk

Derek Hampson
Department of Health,7th Floor, Wellington House, 133-155 Waterloo Road, London, SE1 8UG, UK
Ph : +442079723233
Derek.hampson@dh.gsi.gov.uk

Sheela Reddy
Department of Health,7th Floor, Wellington House, 133-155 Waterloo Road, London, SE1 8UG, UK
Ph: +442079723233
Sheela.reddy@dh.gsi.gov.uk

Dr. Richard Cottrell
Director -General
World Sugar Research Organization
70 Collingwood House, Dolphin Square, London SW1V 3LX
Tel +44 (0)20 7821 6800
Fax +44 (0)20 7834 4137
rcottrell@wsro.org www.wsro.org

USA

Dr. Barbara Schneeman
Director, Office of Nutrition, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration (HFS-850)
5100 Paint Branch Parkway
College Park, Maryland 20740
Ph: +1 (301) 436-2373
barbara.schneeman@fda.hhs.gov

Ms. Nancy Crane
Regulatory Review Scientist
Office of Nutrition, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Ph: +1 (301) 436-1450
nancy.crane@fda.hhs.gov

Sue Ann Anderson, Ph.D.
Team Leader
Infant Formula and Medical Foods Staff
Office of Nutrition, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition
Ph: +1 (301) 436-1453
Sue.Anderson@fda.hhs.gov

Ms Judy Canahuati
Maternal Child Health, Nutrition and HIV Advisor
Office of Food for Peace
U.S. Agency for International Development
Room #7.06.100 RRB
1300 Pennsylvania Avenue, NW
Washington, CD 20523
Tel.: +1 (202) 712 5737
Fax: +1 (202) 216-3039
E-Mail: jcanahuati@usaid.gov

ZAMBIA

John Bwalya Muma
E-mail address: jbwalya@lycos.com
Phone number(s):+260966744355; +260211278139

Grace Banda-Mushibwe
Member Org: International Baby Food Action Network (IBFAN)
Email Add: mushibwegrace@yahoo.com
Phone No. +26 0977 335 482
Mailing Add: C/O National Food and Nutrition Commission
PO Box 32669 LUSAKA Fax : 260-211-221426

Dingiswayo Shawa
BUREAU OF STANDARDS (ZABS), ZAMBIA
E-mail address: dshawa@zabs.org.zm
dngswyo@yahoo.com
Phone number(s:+260(211)231 385/227 075
Mailing address: Zambia Bureau Of Standards, Freedom Way, Lechwe House, P.O Box 50259, 10101 Lusaka, Zambia.

APPENDIX II

Responses to comments made by EWG to second circulation (July 2011 version) of the revised draft

General comments

Ghana is grateful to the EWG for the very useful comments and suggestions. We believe the document is much better as a result of all the inputs received. We tried as much as possible to incorporate the comments. Following the comments received, several sections of the document have been re-organized to make it clearer.

We had several suggestions to modify the **Scope and Description of the Guidelines**.

We decided not to incorporate these yet as other EWG members were in agreement that the text agreed on at the 32nd CCNFSDU be maintained. We are grateful to the CODEX Secretariat for granting the opportunity to have a Physical Working Group meeting to discuss the document further. We have no doubt this will help to move forward the process. We look forward to the participation of all members in the EWG.

This paper summarizes how the comments raised by each EWG member were addressed in the document and in some cases our responses to the comments.

Annex will be taken at the PWG as no consensus was reached on it.

1. EU

   Comment on Scope, description and labeling has been noted and indeed we look forward to further discussions on sections for which no consensus had been reached.

2. Canada

   Discussion on scope and description will be taken at the PWG or CCNFSDU.

   Other comments raised have been incorporated or noted for discussion.

   Comment

   6.6 Vitamins and Minerals

   As a general comment, we would request clarification whether the intent with regard to the addition of vitamins and minerals is similar to that for amino acids, i.e., section 6.3.4 states that the addition of amino acids "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." If yes, perhaps a new section could be included in this regard:

   6.6.2 (new) The addition of vitamins and minerals should be contemplated only when, because of the unavailability of suitable raw materials or ingredients, or for economic or technological reasons, it is not possible to formulate a product that is appropriate to supplement the local diet by providing those nutrients which either are lacking or are present in insufficient quantities.

   Response: We understand Canada's attempt to achieve harmony but the issues are slightly different. No plant source of foods, probably with the exception of cassava are so deficient in amino acid that when combined in the right proportion would require the addition of an amino acid mix. Achieving an adequate protein in FCF is not usually a challenge if anything we are concerned about too much energy coming from protein. The case of vitamins and minerals is not the same. Almost no plant source of foods as raw ingredients in FCF contains adequate bioavailable iron, zinc, vitamin B6 or vitamin B12. Often for technological reasons, animal source foods (meat, fish, liver, eggs etc) are not added to FCF. Even when powdered milk is added, some micronutrients such as iron and zinc are still a problem. The norm is to add vitamins and minerals to FCF because the raw ingredients typically do not provide all these ingredients in bioavailable forms. Thus the addition of vitamins and minerals should be contemplated where traditional complementary foods alone lack adequate amount of bioavailable nutrients.

   Furthermore, section 6.6.1.1 touches on this concern as follows:

6.6.1.1 ~~2~~ The *decision to add* ~~addition of~~ vitamins and minerals *to a Formulated Complementary Food* should take into account local ~~nutrition and health~~ conditions *including the nutrient contribution to the diet from local foods, vitamin and mineral ~~supplements~~ 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 Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987)*.

Comment on 9.2.4.4-

Response: In a previous discussion, an EWG member suggested that we should **not** specify the level of sugar and therefore "less than 10% of the total energy of the product" was deleted (shown as strike through in the document). We suggest this be taken up at the PWG.

3. Uruguay

Most of the comments raised have been addressed in the document.

Section 4.1.4.2.2-Fish protein concentrate: Please can you provide the supporting evidence for use of fish for infants from 9 months onwards?

4. USA

We agree with your suggestion about phytoestrogen. This has been put in square brackets to be discussed further.

Comment on 9.2.3 on Declaration of nutritive value

Response: Noted and will be taken up at PWG.

5. New Zealand

Highlighting priority nutrients for addition

New Zealand has noted that the ultimate aim is to prevent children from becoming malnourished as a result of a nutritionally inadequate diet, and also that the Committee agreed that recently developed Guidelines on complementary feeding from WHO and UNICEF would be considered during the revision of this Guideline.

In the Guiding Principles of the breastfed and non-breastfed child the WHO state that iron, zinc and vitamin B6 are consistently found to be inadequate in the diets of infants and young children globally. The Guiding Principles also state that the use of fortified complementary foods should be included in the diets as one of their twelve guiding principles. Therefore, we consider it important to include a provision within the text on this, especially as there are specific provisions within the text to include specific fatty acids for their nutritional benefit.

6.6.1.4 The addition of iron, zinc and vitamin B6 should be considered as these nutrients are consistently found to be limiting in the complementary diets of infants and young children due to their high nutritional requirements.*

***WHO 2008. Guiding principles for Complementary Feeding of the Breastfed child**

Response: It is likely that the situation will be different for different populations. Putting in a statement as suggested gives no flexibility and in fact it will contradict section 6.6.1.2 (in this revised document) which mentions that the decision to add vitamins and minerals to FCF should take into account the local conditions. A recent document from UNICEF 2011 indicates that "In many developing countries iron, iodine, zinc and vitamin A are the problem nutrients, among others. Iron, iodine, zinc and vitamin D requirements are very difficult to meet with plant-based diets and therefore are problematic in many contexts where animal source foods and fortified foods are scarce" UNICEF 2011 (Programming Guide: Infant and Young Child feeding).

Comment: Selection of appropriate vitamins and mineral compounds

Response: Suggestions have been incorporated in 6.6.3

Comment on Annex Table is noted for further discussions

6. Bolivia

   Comment on section 6.1 addressed.

   Comments on Annex noted for discussion at the PWG.

7. Switzerland

   Revisions on scope and description will be taken at PWG or 33rd CCNFSDU.

   Section 4.2.3.1 The section has been modified. We believe the proposed edits address your concerns.

   5.5.1.1: Addressed. We have added "…and vitamins" to section 5.5.1.1 which addresses some of the disadvantages of extrusion cooking.

   5.5.2.2: We have put improved in square brackets so we will have to make a decision on the word to use: improved or higher nutrient density

   6.5.1 We have put the phrase referred to in square brackets for further discussion.

   All other comments have been addressed in the text.

8. Brazil

   Revisions on scope and description will be taken at PWG or 33rd CCNFSDU.

   Comment on 4.1.3. 2 on basic ingredient: Milk and milk products: We have put the statement on whey protein in square brackets for the group to decide whether to delete or keep that statement.

   5.1.2 on dehulling: Alternative text suggested by other members of the EWG has been incorporated.

   9.1. In the draft Guidelines, the supporting text cited here are all Codex documents. PWG should discuss if non-Codex document should be inserted in the draft Guidelines.

   Annex: Comment is noted for further discussion at PWG or 33rd CCNFSDU.

9. GAIN

   Most of your comments were raised by others and taken into consideration.

   Section 9.1 Comment on nutrient content and nutrient function claim is noted. This is a broader issue to be taken up by the whole group.

10. ESPGHAN

    The description clearly indicates the ages when FCF should be introduced. The additional wording suggested is already covered. The issue of taking into consideration local conditions when nutrient supplements are used have been adequately stated in several sections of the document (6.11, 6.6.1.1 and 6.6.2 of the latest version of the draft document).

    Comment on section 3.4: This paragraph in the draft Guideline provides a definition of the "complementary feeding period". We believe adding the suggested text will distract from this definition.

    Milk and milk products: Other modifications have been done which eliminates the need to specify the sources of the animal milk.

11. IDF

    Milk and milk products: The text now reads "*Milk and milk products are sources of high quality proteins and micronutrients*".

    The section on fish meals and fish protein concentrate has now been captured in only one paragraph section 4.1.4.3.

    Comment on Food additives and flavours can be taken up at the PWG.

12. ISDI

    Comment on scope and description to be taken up later.

We agree that fruits and vegetables are an important component of the complementary feeding diet. We should however be promoting its consumption in the fresh form.

5.1.2 on dehulling: Controlling the amount of dietary fiber in FCF is important as high levels interfere with mineral bioavailability.

6.5.2 Issue on dietary fiber has been put in square brackets for further discussion.

9.2.1.2 and 9.2.3 The suggested new texts have been put in square brackets for the consideration of the PWG.

Comment on Annex table noted for further discussion at PWG.