

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of
the United Nations



World Health
Organization

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Agenda Item 6

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty second Session

Santiago, Chile

1 – 5 November 2010

**Proposed Draft Revision of the Guidelines on Formulated Supplementary Foods
for Older Infants and Young Children (CAC/GL 08-1991) at Step 4**

- Comments at Step 3 of the Procedure -

Comments from:

ARGENTINA

BOTSWANA

BRAZIL

CANADA

CHILE

CHINA

EUROPEAN UNION

INDONESIA

MALAYSIA

PHILIPPINES

SOUTH AFRICA

UNITED STATES OF AMERICA

WFP – World Food Programme

IBFAN – International Baby Food Action Network

ISDI - International Special Dietary Foods Industries

ARGENTINA

Text in italics: Comments by Argentina

Changes in Argentina's text: bold and italics

Argentina welcomes the opportunity to make the following comments and wishes to point out that, despite being generally in agreement with the content of said document, the comments made last August on the points detailed below are reiterated.

REVISED VERSION OF THE GUIDELINES SUBMITTED TO THE 32ND SESSION OF THE CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES GUIDELINES ON FORMULATED SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN (CAC/GL 08-1991)¹

Title: what is the change in relation to the title?

GUIDELINES ON [SPECIFICALLY] FORMULATED [FORTIFIED] COMPLEMENTARY SUPPLEMENTARY [COMPLEMENTARY SUPPLEMENTED] 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 [specifically] formulated [fortified] complementary ~~supplementary~~ [complementary supplemented] foods [formulated] 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.

- Argentina agrees to changing the term "Complementary" to "Supplementary" because this is not only WHO terminology, but is also the correct form of referring to such foods at the national and international levels.

By contrast, it also considers it appropriate for such foods to bear a distinctive denomination such as "Specifically Formulated Complementary Food" insofar as they provide a determined quantity of nutrients and energy value that are used on older infants as complements for breast milk when this does not cover the necessary requirements. And they should be thus differentiated from complementary preparations or foods intended for a population of "healthy" older infants and small children in countries that do not possess an identified deficiency.

3. DESCRIPTION

3.1 [Specifically] *Formulated* [fortified] *Complementary* [Complementary Supplemented] *Foods for Older Infants and Young Children* means foods **that are** suitable [for use during the ~~infant's complementary feeding weaning period and~~] for feeding **older infants and** young children as a complement [supplemented complement] ~~supplement~~ to breastmilk or breastmilk

substitutes **to provide those nutrients and energy which either are lacking or are present in insufficient quantities in local diets. These foods include foods such as porridges, ready-to-use products (pastes and compressed bars), and a food-based home fortificants to enrich** ~~other foods available in the country where the product is sold or otherwise made available.~~ They are not suitable for use for infants before six months of age, the beginning of the weaning period. These foods provide those nutrients which either are lacking or are present in insufficient quantities in the local diets basic staple foods. **They are not suitable for use by infants under six months of age.**

- Argentina considers that, in compliance with the "Codex General Principles for the Addition of Essential Nutrients to Foods" (CAC/GL 09-1987), currently under review by the other electronic working group presided over by Canada, Chile and New Zealand, "enrich" and "fortified" are considered by to synonymous:

2.5 Fortification or enrichment is understood to be the addition of one or more essential nutrients to a food, both whether it is contained normally in the food or not, with the aim of preventing or correcting a demonstrated deficiency of one or more foods...

- On the other hand, it is considered that whatever is decided in relation to these two terms in that group ought to be taken into account before adopting a decision in this respect, with the aim of warranting coherence in all the Codex texts.

4. SUITABLE RAW MATERIALS AND INGREDIENTS

4.1.3 Oil Seed Flours and Oil Seed Protein Products

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

- Argentina considers that, given that "full fat and defatted" refers only to flours, as the concentrates and isolated substances are prepared on the basis of defatted flour, the following ought to be said about soya flour:

"Soya beans: flour (full fat and defatted), concentrate, isolate"

Groundnuts: defatted flour, isolate (full fat and defatted), isolate

Sesame seed: whole full fat ground and defatted flour

Cottonseed: defatted flour

Sunflower seed: full fat and defatted flour, full fat

Canola Low erucic rapeseed: full fat flour

5. TECHNOLOGIES FOR AND EFFECTS OF PROCESSING

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

Argentina considers it appropriate to and suggests replacing the term "crude fibre" in the paragraph above and in the rest of the text where it is mentioned as "dietary fibre", thus establishing coherence with the form in which these are denominated.

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**.

- Argentina reiterates that it deems it appropriate to cite, in addition to the previous points, "partial hydrolysis of phytates" as one of the effects of the technology. Aware of this, we suggest adding this under another item.

. Partial hydrolysis of phytates

6. FORMULATION

6.4 Fat

~~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)~~

- Argentina considers that paragraph 6.4.3 must not be moved to the Labelling section because that itself is a consideration of formulation of the product. In any case it would be convenient to add a phrase in the "Labelling" section that says the following:

9.2.4.6 "Where appropriate, instructions for the addition of fats and oils during the preparation of the food, according to 6.4.3, should be included."

9. LABELLING

9.2.2 List of Ingredients

9.2.3 Declaration of Nutritive Value

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

- Argentina proposes inclusion of the words reconstituted and when appropriate in the following paragraph.

(c) in addition to any other nutritional information required by national legislation, the total quantity **per feeding of** in the ~~food as sold or in the final product~~ **product reconstituted, when appropriate ready for consumption** of each vitamin and mineral added in accordance with Section 6.6 expressed in metric units.

TABLE

**NUTRIENTS VITAMINS AND MINERALS REFERENCE DAILY REQUIREMENTS
NUTRIENT INTAKE FOR YOUNG CHILDREN 1-3 YEARS OF AGE**

Copper mg 0.56

Argentina reiterates that it considers it convenient to revise the value for copper, given that it does not correspond to the quotation indicated (FAO/WHO 2004 does not cite figures for copper), nor does it correspond to the value of the Institute of Medicine for which a value for children from 1 to 3 years amounting to 0.34 mg/day is established)

BOTSWANA

Botswana would like to take this opportunity to thank Ghana for chairing the Electronic working Group (EWG) that prepared this comprehensive draft revision now at step 4 of the Codex Procedure. Botswana would also like to thank all other EWG members for the good work.

Botswana suggests that:

1. The proposed revised guidelines be assimilated in the Codex Standard for Processed Cereal Based Foods for Infants and Young Children to form one combined Standard with several parts to be titled: **Codex Standard for Complementary Foods for Older Infants and Young Children.** i.e.
 - **Part A-** Standard for Healthy Normal Older Infants and Young Children;
 - **Part B-** Standard for Underweight Older Infants and Young Children (as proposed by India) (that should be used only when medically indicated and not marketed as routine complementary foods). and
 - **Part C -**Standard for Therapeutic Foods for the Treatment of Severe Acute Malnutrition (that should be used only when medically indicated and not marketed as routine complementary foods).

The suggestion above is based on the following observations:

- The draft Guidelines on Formulated Supplementary Foods for Older Infants and Young Children and the Codex Standard for Processed Cereal Based Foods for Infants and Young Children are similar in many ways including the target age groups (6-36 months old babies);
 - The Guidelines format, unlike other Codex guidelines, is similar to the standard format for Codex Commodity Standards,;
 - The two food standards (the Guidelines and the Standard) for the same age groups would create confusion in the market place, for the parents; care givers and health care providers; particularly in developing countries where, in the absence of effective and appropriate national laws, the use of Codex standards is often the norm;
 - This confusion will undermine optimal infant and young child feeding including breastfeeding and complementary feeding practices using energy and nutrient rich indigenous and culturally appropriate foods; resulting in increased burden of malnutrition in developing countries.;
 - This scenario may be exploited to have double standards; one for babies in developed countries and one for the babies developing counties, as was initially suggested which Botswana consider being unethical.
2. Improvement could be done on the standard including the compositional requirements such as reducing sugar levels, increasing cereal content and control of toxins and contaminants in raw materials and finished products; such as melamine in milk, mycotoxins in cereals and trypsin inhibitor and hemagglutinins in soya.
 3. The addition of a clause prohibiting nutrition and health claims for Complementary Foods for Infants and Young Children because of the following reasons::
 - Nutrition and health claims for baby foods are by nature misleading and therefore not necessary;
 - The scientific evidence used to justify nutrition and health claims is often not independent;
 - Nutrition and health claims are marketing tools;
 - Nutrition and health claims are a contravention of the WHO International Code of Marketing of Breastmilk Substitutes;
 - Nutrition and health claims are in conflict with national nutrition policies
 - Nutrition and health claims are prohibited in relevant Codex Standards and Guidelines on nutrition and health claims.

4. The addition of a clause prohibiting promotions and idealizing pictures or texts of complementary foods for Infants and Young Children because of the following reasons:
 - Promotion and increased availability industrially formulated prepackaged complementary foods for infants and young children in the market would result in the competition of these foods with recommended duration of sustained breastfeeding from 6 to 24 months and the use of indigenous energy dense and nutrient rich complementary foods.
 - Although the introduction of complementary foods is recommended after the age of 6 months, breastmilk remains the most important food providing optimal micronutrients, immunology and psychological stimulation critical for cognitive development;
 - It has been demonstrated that interventions to ensure optimal nutrition status and prevent under nutrition can be achieved by improving breastfeeding rates and the use of indigenous energy dense and nutrient rich complementary foods;
 - Optimal feeding combined with nutrition education and primary health such as elimination of parasites and the treatment and prevention of malaria are the most effective and least costly in improving nutritional status and child health. The use of costly commercial fortified products is not sustainable and uses scarce resources in resource poor situations.

BRAZIL

We suggest to use the term “complementary food” to be consistent with the WHO definition.

4.1.1.2 Besides carbohydrates (mainly consisting of starch) cereals contain a significant quantity of protein (8-12%). Whereas rice has a satisfactory essential amino-acid composition, ~~However~~, all other cereals are as a rule ~~limiting~~ limiting in lysine.

Brazilian Comments

In relation to the paragraph 4.1.1.2, we reaffirm our suggestion to revise the text “Whereas rice has a satisfactory essential amino-acid composition, however, all other cereals are as a rule limiting in lysine”, because rice is deficient in lysine as well as other cereals.

4.1.6.1 Dairy Milk and milk products **are nutrient dense and good sources of high quality proteins and other micronutrients. They and are considered** beneficial to growth and can be added to complementary food. Dairy products They can be added as dried skimmed milk, full fat milk and semi-skimmed milk solids **Whey proteins concentrates are a readily available source of protein with a high bioavailability which can be used to increase and improve the protein level of formulated complementary foods.**

Brazilian Comments

We suggest to delete the sentence “They and are considered beneficial to growth and can be added to complementary food” and the term “good”. We understand that it is not appropriate to use an adjective, e.g. “good”, to qualify the source of an ingredient. We also think that the sentence “They and are considered beneficial to growth and can be added to complementary food” is not appropriate as it may stimulate the use of milk and dairy products, and other ingredients can also be considered beneficial to growth. We understand that it is not necessary to describe the beneficial of ingredients in the guidelines.

4.2.2 Digestible carbohydrates including sugars

Energy density should preferably be increased by the addition of fat and/or digestible carbohydrates. If nutritive sweeteners are used, they should be used in moderation. provide less than 10% of the total energy of the product⁴.

⁴ WHO TRS 916. Diet Nutrition and the Prevention of chronic Diseases

Brazilian Comments

We suggest to replace the term “nutritive sweeteners” for “sugars as defined in the Codex Alimentarius and/or other carbohydrate sweeteners such as honey”, as recommended by the Codex Committee on Processed Fruits and Vegetables (Alinorm 05/28/27 and CX/PFV 04/22/3), as described below:

Paragraph 7 of the CX/PFV 04/22/3: “*other Codex Committees prefer to avoid the use of the term “(nutritive) carbohydrate sweeteners”, “nutritive sweeteners”, “natural sweeteners”, etc, to prevent confusion regarding the nature of these products as they may be described differently by regulatory agencies and/or may encompass compounds that are regarded as food/food ingredients (e.g. sugars (sucrose), honey, (high) fructose syrups, invert sugar, fruit juice concentrates, etc) or food additives (D-Tagatose, sugar, alcohols, etc). Reference is thus made to “sugars (including syrups) as defined in the Codex Standard for Sugars, honey as defined in the Codex Standard for Honey, and sweeteners as listed in the Section on Food Additives”.*

Besides that, the document “WHO TRS 916. Diet, Nutrition and the Prevention of chronic Diseases”, used as a reference in the item 4.2.2, is about the consumption of sugar in diets of the general population and it’s not related to the amount of sweeteners in products. Thus, we ask for clarifications about the use of this reference to establish limit for sugars in products for older infants and Young children.

4.2.3 **Flavours: Ethylvanillin and vanillin (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.

4.2.4 Food additives allowed for use in Codex STAN 074-1981, Rev. 1-2006 are permitted for use in formulated Complementary foods.

Brazilian Comments

We reaffirm our previous comment that the use of additives, including flavors, should be set in Codex Standards or in national legislation. So, we suggest to replace the paragraphs 4.2.3 and 4.2.4 for the following paragraph as proposed below:

“4.2.3. Additives: the use of additives may be allowed if specifically provided for in relevant Codex Standards or in national legislation.”

4.2.5 **Other ingredients of food quality:** provided they have been proven to be suitable for their intended purpose.

Brazilian Comments

We reaffirm our suggestion to include the word “safe” in the paragraph 4.2.5, as proposed below:

“4.2.5. Other ingredients of food quality: provided they have been proven to be suitable and safe for their intended purpose.”

9. LABELLING

Brazilian Comments

We emphasize that the guidelines must take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), in the Global Strategy for Infant and Young Child Feeding and in the World Health Assembly Resolution, WHA 54,2 (2001). Thus, we suggest to include a specific provision in the item 9 about that.

Furthermore, we suggest to include a prohibition on the use of health claims in FCF. Taking into account the paragraph 8.1.2 of the Codex Stan 74-1981, Rev. 2006, we suggest to include a permission on the use of nutrition claims if provided for in national legislation.

Annex – TABLE

Brazilian Comments

In respect with the amount of vitamins and minerals to be added in Formulated Complementary Foods, we suggest to use the table based on the Recommended Nutrient Intake (RNI), since the WHO/FAO 2006 document does not provide EAR values for all micronutrients.

CANADA

Canada would like to express its appreciation to Ghana for its leadership in the preparation of the Proposed Draft Revision of the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children.

Canada would like to submit for consideration of the Committee the following comments on the Proposed Draft Revision:

TITLE

Canada supports the acceptance of the WHO term “complementary foods” to replace “supplementary foods” for foods that are used to feed an infant and young child when breastmilk is no longer sufficient as the sole source of nutrition.

We consider that it is important that the title of this document as well as the description of “complementary foods” clearly distinguished the foods that are the subject of these guidelines from locally available unprocessed foods that are fed to infants during the complementary feeding period. In this regard, the use of the term “formulated” would appear to perform this task. Since these formulated complementary foods may or may not be fortified or supplemented, the use of these terms in the title may be confusing. In addition, we consider the term “specifically” to qualify “formulated”

to be unnecessary and redundant, i.e., these are foods specifically for older infants and young children.

Canada suggests the following title for the document:

Revised Draft “GUIDELINES FOR FORMULATED COMPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN”

If the above terminology is found acceptable, consecutive changes will have to be made throughout the document.

1. PURPOSE

The same comments as above apply with regard to the text in square brackets in this section. The formulated complementary foods may or may not be fortified. However, since the Guidelines provide guidance regarding fortification, we would suggest the following revision to the proposed text:

“To provide guidance on nutritional and technical aspects of the production of formulated complementary foods for older infants and young children as defined in Section 3.1, including:

i. Formulation of such foods, including their fortification with essential nutrients as required, based on the nutritional requirements of older infants and young children;.....”

2. SCOPE

Since micronutrient may be sold in liquid solutions as well as powders, we would suggest also excluding this format. In line with this and the above comments, we would suggest the following revision to the text:

“The provisions of these Guidelines apply to formulated complementary foods for older infants and young children as defined in Section 3.1. below. Products in powder or liquid formats that provide only micronutrients are not covered by these Guidelines.”

3. DESCRIPTION

In line with the above comments, we would like to suggest the following revised text for consideration. We have added the text “as well as local foods” since these formulated complementary foods would be used in addition to breastmilk, breastmilk substitutes and local foods.

“3.1 Formulated Complementary Foods for Older Infants and Young Children means foods that are suitable for feeding older infants and young children as a complement to breastmilk or breastmilk substitutes as well as local foods, to provide those nutrients and energy which either are lacking or are present in insufficient quantities in local diets. These formulated complementary foods include porridges, ready-to-use pastes and compressed bars, and food-based home fortificants. They are not suitable for infants under six months of age.”

4. SUITABLE RAW MATERIALS AND INGREDIENTS

- In subsection 4.1.1.1, we would like to suggest the addition of the text “and amino acid bioavailability” just before “and mineral absorption”:

“4.1.1.1 All milled cerealscan lower the protein digestibility and amino acid bioavailability and mineral absorption.”

- In subsection 4.1.2.1, we would suggest that the Committee consider including the nitrogen conversion factor, i.e., N X 6.25 or N X 5.7

- In subsection 4.1.2.2 , please add “L” before “methionine”.
- In subsection 4.1.2.4. add “faba beans” since in many countries including Canada field beans are commonly considered to belong to Phaseolus sp. Also the correct term is “vicine” not “vicin”

“4.1.2.4 Field beans or faba beans (Vicia faba L.) (vicine and co-vicine).”

- In subsection 4.1.3.1, we are not aware of any industrial technology of preparing full-fat concentrate or isolate, therefore suggest deleting “full fat”.
- In subsection 4.1.6, in the 1st sentence, we would suggest deleting the word “other” just before “micronutrients” since no other micronutrients are mentioned. In the final sentence in this section, the word “level” should be deleted and replaced with “quality”:

“Whey proteins.....can be used to improve the protein quality.....”

- In subsection 4.2.1 we would suggest using text that parallels that in subsection 4.1.6., i.e.,

“4.2.1 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.”

- In subsection 4.2.3, since the level of ethylvanillin and vanillin is indicated, there would appear to be no need to require an additional safety assessment.
- In subsection 4.2.5 , we would suggest adding the word “safe”:

“4.2.5 Other ingredients of food quality: provided they have been proven to be safe and suitable for their intended purpose.”

5. TECHNOLOGIES FOR AND EFFECTS OF PROCESSING

In subsection 5.1.2, we suggest inserting “and amino acid bioavailability” immediately before “and mineral absorption”.

6. FORMULATION

With regard to subsection 6.3.2 PDCAAS, it is our understanding that FAO/WHO will be holding an Expert Consultation on Protein Quality Assessment of Foods in April, 2011, and it is possible that PDCAAS would be revised. Therefore, any decision about this assessment should be postponed till the recommendation of that Expert Consultation. The Committee should discuss whether a protein with a PDCAAS of .70 is a high quality protein.

With regard to subsection 6.3.4, we would suggest deletion of DL-methionine since there are conflicting reports about the full utilization of DL-methionine in children.

In subsection 6.3.5, the Committee may wish to consider whether 10% energy from protein is sufficient considering the poor protein digestibility of pulses?

In subsection 6.4.2, 300 mg of linoleic acid (LA) per 100 kcal represents 2.7% of total energy. This energy level for LA is lower than the AI of 3.0-4.5% of total energy recommended by FAO/WHO (2008 Joint FAO/WHO Expert Consultation on Fats and Fatty Acids in Human Nutrition) for older infants 6-12 months of age and children 12-24 months of age. The minimum AI of 3% energy corresponds to 333 mg per 100 kcal. Considering this, the Committee should consider the following change to the first part of Section 6.4.2.:

“The level of linoleic acid (in the form of glycerides) should not be less 333 mg per 100 kcal or 1.6 g per 100 g of dry product.....”

CHILE

Relevance and topicality. Assess whether the text proposed contributes with health measures aimed at having an effect on the problem. The problem is presented as a risk profile in the introduction.	This document does not seem clear, it could be an internal regulation. It complicates the complementary and supplementary definitions.
Another point of view would be to estimate whether the standard will improve or worsen the international exchange of this kind of foodstuff, in the medium and long term.	It does not contribute.
Consider whether the measures suggested in the preliminary study are feasible for application by developing countries. The review might consider technical complexity, available laboratory capacity and economic cost among other things.	It does not seem necessary to lay down rules for this, and it may only need some local regulation, in terms of the country's nutritional situation.
There should not be any duplication of existing regulations.	Does not apply
If there are deficiencies, such as aspects that are lacking, or exist but are insufficiently considered, suggest how this could be improved or complemented with national and regional contributions.	A very clear definition of the scope of action is required, and whether it covers fortified foods or those specially formulated for a specific group.
Introduction	We agree that it is necessary to cover the scourge of malnutrition, but we believe that existing regulations already include this. We emphasise the need for clarity in definitions, according to the title of the document.
Scope of application and objective	We note the need to clarify the scope of action and the objectives.
Proposal for national position	We suggest revising the need to develop such a specific standard.

CHINA

China fully supports the proposal to revise the CODEX Guidelines on formulated supplementary foods for older infants and young children.

Recently years, Chinese government has been noticed that the growth and development of Chinese infants older than 6 months and young children are trailed the WHO growth patent related to the low nutritional density in the complementary foods. For that reason, China has been issue a new standard on the Complementary Food Supplements, the General Standard for Complementary Food Supplements (GB/T 22570-2008). The Chinese new standard was aimed on using complementary food supplements to improve the quality of the complementary foods for the infants and young

children to catch up the standard growth patent. A population based placebo-controlled intervention study in West-China has documented that a soy based complementary supplement could improve the growth and cognitive function, and decrease the prevalence of iron deficiency anemia in young children. China would like to provide such kind of standard as a reference for discussion.

China delegation also noticed that the same problem do consist in the East-south Asian and African countries. We really believe that the REVISE OF THE CODEX GUIDELINES ON FORMULATED SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN would be helpful for the improving of the nutritional status of infants and children.

European Union

European Union competence

European Union vote

The European Union (EU) would like to thank Ghana for the preparation of this document. The EU would like to send the following comments for consideration.

The EU considers that the title should reflect as much as possible the purpose and scope of the revised guidelines as agreed in the 31st Session of the CCNFSDU.

The proposal includes in its scope foods such as porridges and ready-to-use products such as pastes, compressed bars in addition to food-based home fortificants. The nutritional composition of these products, as described in section 6 of the document, is different from the nutritional composition of the complementary foods covered by the standards on processed cereal-based foods and canned baby foods. In addition the target population is different.

The EU believes that in order to avoid any confusion between the different "complementary" foods for older infants and young children, the type of foods covered by the revised guidelines as well as the intended group of the population have to be clearly specified.

0. TITLE

The WHO definition defined "supplementary foods" as formulated foods used to supplement the diet in order to rehabilitate malnourished persons or to prevent a deterioration of nutritional status of those most at risk. Consequently, the EU believes that the terms 'supplementary foods' and 'older infants and young children' are sufficient to capture the type of foods and the target group of the population covered by the present guidelines. The EU believes that the addition of the term 'complementary' and/or 'fortified' would create confusion as regards the scope of the guidelines with the scope of other Codex Standards addressed to Infants and Young Children.

The EU suggests consequently maintaining the current title:

Formulated Supplementary Foods for Older Infants and Young Children

3. DESCRIPTION

The EU suggests the following wording:

Formulated supplementary foods means foods suitable for use during the complementary feeding period and for feeding older infants and young children as a supplement to breast-milk or breast-milk substitutes or other food available in the country where the product is sold. These foods are specifically formulated foods to provide those nutrients which either are lacking or are present in insufficient quantities in the local diets. These foods include porridges, ready-to-use products such as pastes and compressed bars, and food based home fortificants. They are not suitable for use for infants before the beginning of the complementary feeding period.

As the complementary feeding period is defined in this section 3, the EU considers more adequate to refer clearly to it instead of adding the statement "not suitable for infants under six months of age". Furthermore, the EU suggests the following wording for the definition of *complementary feeding period* to improve clarity.

Complementary feeding period means the period when older infants and young children progress from exclusive feeding of breast milk and/or breast milk substitutes onto a normal family diet.

4.2.1 ANIMAL SOURCES FOODS

The EU believes that the statement on – promoting the consumption of animal source foods during the complementary feeding – goes beyond the purpose of this section. Therefore, the EU would suggest the following:

Animal source foods such as meat, fish, poultry and eggs are good sources of protein to be included in the diet of older infants and young children during the complementary feeding period.

X. INFORMATION FOR UTILISATION

The EU suggests adding a new section related to information for utilization consistent with existing Standard on processed cereal-based foods.

The label should indicate clearly from which age the product is recommended for use. This age should not be less than six months for any product. In addition, the label should include a statement indicating that the decision when precisely to begin 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.

9. LABELLING

The EU would appreciate if further clarification could be provided on the last sentence "The appropriate description should be in accordance with national legislation." as the description of the food will already be clearly defined in section 3.

9.2.1.1. The name of the food to be declared on the label shall indicate that the food is a **formulated supplementary food** for older infants and young children. The appropriate description should be in accordance with national legislation.

9.2.1.2

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

The EU suggests deleting the statement made in point (c) as point (b) already makes clear that the foods are to be used during the complementary feeding period which is as mentioned before well defined in section 3.

9.2.3 DECLARATION OF NUTRITIVE VALUE

(b) the amounts of protein, carbohydrates and fat, [~~and the amount of linoleic and alpha-linolenic acid~~], expressed in grammes or [milligrammes] where appropriate.

The EU does not agree with the proposal to include the declaration of linoleic acid and alpha-linolenic acid. This goes beyond what is required in the existing Codex text for nutrition labelling in products intended for infants and young children. The EU questions also the consumer understanding of such detailed information and the background to choose to declare information on linoleic acid and alpha-linolenic acid to other nutritional information.

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.

INDONESIA

	Text	Comments
Title	GUIDELINES ON [SPECIFICALLY] FORMULATED [FORTIFIED] COMPLEMENTARY SUPPLEMENTARY [COMPLEMENTARY SUPPLEMENTED] FOODS FOR OLDER INFANTS AND YOUNG CHILDREN (CAC/GL 08-1991) ¹	Indonesia proposes the title of the guidelines, as follow : GUIDELINES ON FORMULATED COMPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN (CAC/GL 08- 1991)
1. PURPOSE	To provide guidance on nutritional and technical aspects of the production of [specifically] formulated [fortified] complementary supplementary [complementary supplemented] foods [formulated] for older infants and young children as defined in Section 3.1, including:	To be inline with the title, so it will be read as : To provide guidance on nutritional and technical aspects of the production of formulated complementary foods for older infants and young children as defined in Section 3.1, including:
2. SCOPE	The provisions of these Guidelines apply to [specifically] Formulated [fortified] Complementary Supplementary [complementary supplemented] Foods for Older Infants and Young Children as defined in Section 3.1 below. Micronutrient powders are not covered by this Guideline.	To be inline with the title, so it will be read as : The provisions of these Guidelines apply to Formulated Complementary Foods for Older Infants and Young Children as defined in Section 3.1 below. Micronutrient powders are not covered by this Guideline.
3. DESCRIPTION	3.1 [Specifically] <i>Formulated</i> [fortified] <i>Complementary</i> [Complementary Supplemented] <i>Foods for Older Infants and Young Children</i> means foods that are suitable [for use during the infant's complementary feeding weaning period and] for feeding older infants and young children as a complement [supplemented complement] supplement to breastmilk or breastmilk substitutes to provide those nutrients and energy which either are lacking or are present in insufficient quantities in local	To be inline with the title, so it will be read as : 3.1 <i>Formulated Complementary Foods for Older Infants and Young Children</i> means foods that are suitable for feeding older infants and young children as a complement to breastmilk or breastmilk substitutes to provide those nutrients and energy which either are lacking or are present in insufficient quantities in local diets. These foods include porridges, ready-to-

	Text	Comments
	<p>diets. These foods include foods such as porridges, ready-to-use products (pastes and compressed bars), and a food-based home fortificants to enrich [fortify] other foods available in the country where the product is sold or otherwise made available. They are not suitable for use for infants before six months of age, the beginning of the weaning period. These foods provide those nutrients which either are lacking or are present in insufficient quantities in the local diets basic staple foods. They are not suitable for use by infants under six months of age.</p>	<p>use pastes and compressed bars, and food-based home fortificants. They are not suitable for use by infants under six months of age.</p>
4.1.2 Pulses	<p>Pulses, including chick peas, lentils, peas, cow peas, mungo beans, green gram and kidney beans contain are a good source of appropriate proteins (20-24 35%) protein.</p>	<p>Indonesia agrees with the proposed change. However the protein contain should not be stated in the maximum range. Thus we propose the following changes :</p> <p>4.1.2.1 Pulses, including chick peas, lentils, peas, cow peas, mungo beans, green gram and kidney beans contain at least 20 % of protein.</p>
4.1.5.3	<p>Partially hydrogenated oils containing (trans) fatty acids should not be used in formulated complementary [complementary supplemented] foods³ for older infants and young children (Codex STAN 074-1981, Rev. 1-2006)</p>	<p>Indonesia proposes to remove the texts in the square bracket to be inline with the title, so the texts will be read as :</p> <p>4.1.5.3 Partially hydrogenated oils containing trans-fatty acids should not be used in formulated complementary foods³</p>
4.2.3	<p>Flavours: Ethylvanillin and vanillin (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.</p>	<p>Indonesia would like to add the words “maximum” before 7 mg/100g RTU and point 4.2.3 will be read as :</p> <p>Flavours: Ethylvanillin and vanillin (<u>maximum</u> 7 mg/100g RTU), natural fruit and vanilla extract, may be used provided they have been evaluated for their safety-in-use.</p>
4.2.5	<p>Other ingredients of food quality: provided they have been proven to be suitable for their intended purpose.</p>	<p>Indonesia would like to ask clarification regarding the type of food and whom given the approval since it states that</p>

Text		Comments
		other ingredients have been proven be suitable for their intended purpose.
6.1.2	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 can ingest easily in two or more feedings per day . This range provides an allowance for the various types of [fortified 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 applies to products with lower energy density (e.g, cereal-based products)	Indonesia agrees to open the square brackets by changing “the fortified” with “formulated” so the text will be read as : 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 fed breast milk can ingest easily in two or more feedings per day . This range provides an allowance for the various types of <u>formulated complementary</u> 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 applies to products with lower energy density (e.g, cereal-based products)
6.1.5	Care must be taken to ensure that the combined total amounts of the Complementary food micronutrient fortification, micronutrient intake from the formulated complementary [supplemented] food, found in the local diet (including breast milk and/or breast milk substitutes), and other sources micronutrients that may be provided separately do not regularly exceed the recommended dosage relevant upper levels of micronutrient result in excessive intake for older infants and young children.	Indonesia agrees with this section with removing the text in the square bracket, so the texts will be read as : 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.
6.5.1	Starch is likely to be a major constituent of many complementary [complementary supplemented] supplementary foods for older infants and young children. To	Indonesia proposes to delete the texts in the square bracket.

Text		Comments
	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.	
6.5.2	Increasing the intake of dietary fibres ¹⁰ increases enhances stool bulk, may cause flatulence and decrease appetite. They also may Fibre load also can affect the efficiency of absorption of important various nutrients of significance from in diets with a marginal nutrient contents. so The dietary fibre content of the [formulated] [fortified complementary] food should therefore be reduced to a level not exceeding 5 g per 100 g on a dry weight basis.	Indonesia proposes to open the square brackets but to delete the word “fortified”, so texts will be read as : Increasing the intake of dietary fibres ¹⁰ increases stool bulk, may cause flatulence and decrease appetite. Fibre load also can affect the efficiency of absorption of important nutrients from diets with a marginal nutrient contents. The dietary fibre content of the <u>formulated complementary</u> food should therefore be reduced to a level not exceeding 5 g per 100 g on a dry weight basis.
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 line to emphasize the nutrients to be considered in the development of a formulated complementary [complementary supplemented] food.	Indonesia proposes to remove the texts in the square brackets, so the text will be read as : The Table in the Annex to these Guidelines contains the reference nutrient intakes (RNIs) for the vitamins and minerals for older infants and young children. It is important to keep in mind that the Table is simply a guide to emphasize the nutrients to be considered in the development of a formulated complementary food.
7. HYGIENE	It is recommended that Formulated Complementary [complementary supplemented] Supplementary Foods for Older Infants and Young Children comply with the following mandatory hygiene requirements:	Indonesia proposes to delete the texts in the square brackets
9.1	It is recommended that the labeling of Formulated Complementary [complementary supplemented] Supplementary Foods for Older Infants and Young Children be in	Indonesia proposes to delete the texts in the square brackets

Text		Comments																		
	accordance with the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985).																			
Annex	<table><tr><td colspan="2">Table</td></tr><tr><td>Nutrients Vitamins and minerals</td><td>Reference daily requirements nutrient intake for young children 1-3 years of age</td></tr><tr><td>Vitamin A µg retinol equivalent</td><td>400 µg retinol equivalent</td></tr><tr><td>...</td><td>...</td></tr><tr><td></td><td></td></tr></table>	Table		Nutrients Vitamins and minerals	Reference daily requirements nutrient intake for young children 1-3 years of age	Vitamin A µg retinol equivalent	400 µg retinol equivalent			<p>Indonesia proposes to add the square bracket between the units, following the proposal :</p> <table><tr><td>Nutrients Vitamins and minerals</td><td>Reference daily requirements nutrient intake for young children 1-3 years of age</td></tr><tr><td>Vitamin A (µg retinol equivalent)</td><td>400 µg retinol equivalent</td></tr><tr><td>...</td><td>...</td></tr><tr><td></td><td></td></tr></table> <p>Indonesia would like to inform that we use Reference Nutrient Intake to establish nutrient levels.</p>	Nutrients Vitamins and minerals	Reference daily requirements nutrient intake for young children 1-3 years of age	Vitamin A (µg retinol equivalent)	400 µg retinol equivalent		
Table																				
Nutrients Vitamins and minerals	Reference daily requirements nutrient intake for young children 1-3 years of age																			
Vitamin A µg retinol equivalent	400 µg retinol equivalent																			
...	...																			
Nutrients Vitamins and minerals	Reference daily requirements nutrient intake for young children 1-3 years of age																			
Vitamin A (µg retinol equivalent)	400 µg retinol equivalent																			
...	...																			

MALAYSIA

GENERAL COMMENT

Malaysia proposes that this committee should keep to the intention of the original guideline. Therefore, we propose that we keep to the original title as well as the original scope.

We take note of the WHO definition of supplementary food which is intended to rehabilitate malnourished children or to prevent a deterioration of nutritional status of at-risk population. However, for the purpose of this standard, we feel that supplementary food may be defined as a food which is formulated to supplement the older infants and young children to provide those nutrient and energy which either are lacking or are present in insufficient amount in their daily diet. This is to ensure that the older infants and young children obtain all the nutrients needed for their optimal growth and development.

It can also be noted that the term “complementary” is used in the CODEX Standard for Processed Cereal Based Food for Older Infants and Young Children. This is clearly distinct from this “supplementary food” standard as it is meant for different purposes. Therefore, we propose that the term “complementary” not to be used in this guideline.

PHILIPPINES

The Philippines supports the revised version of the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 08-1991) drafted by the Electronic Working Group with the following amendments:

1. Title

From	To
Guidelines on [Specifically] Formulated [Fortified] Complementary Supplementary [Complementary Supplemented] Foods for Older Infants and Young Children (CAC/GL 08-1991)	Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 08-1991)

We proposed to delete the square brackets and the words *specifically*; *fortified*; *complementary supplemented* as shown above:

Justification: With the words “specific” and “fortified,” the proposed draft may limit the guidelines to fortified complementary foods. The word “Fortified” has specified level (for instance, some local regulations like the Philippines require specific values for the product to be called “fortified”). This may imply that those products which fall below the fortification level cannot be covered by these guidelines. Hence, terms “specific” and “fortified” are proposed to be removed. The word “supplementary” is likewise changed to “complementary.”

2. Purpose

From	To
To provide guidance on nutritional and technical aspects of the production of [specifically] formulated [fortified] complementary supplementary [complementary supplemented] foods [formulated] for older infants and young children as defined in Section 3.1.	To provide guidance on nutritional and technical aspects of the production of formulated complementary foods for older infants and young children as defined in Section 3.1.

3. Scope

From	To
The provisions of these Guidelines apply to [specifically] Formulated [fortified] Complementary Supplementary [complementary supplemented] Foods for Older Infants and Young Children as defined in Section 3.1 below. Micronutrient powders are not covered by this Guideline.	The provisions of these Guidelines apply to Formulated Complementary Foods for Older Infants and Young Children as defined in Section 3.1 below. Micronutrient powders are not covered by these Guidelines.

Justification: Editorial correction was made changing the words “this guideline” to “these guidelines” for consistency with the first sentence.

4. Description

From	To
3.1 [Specifically] <i>Formulated</i> [fortified] <i>Complementary</i> [Complementary Supplemented] <i>Foods for Older Infants and Young Children</i> means foods that are suitable [for use during the infant's complementary feeding weaning period	3.1 Formulated Complementary Foods for Older Infants and Young Children means foods that are suitable for feeding older infants and young children <u>in addition</u> to breastmilk or breastmilk substitutes to provide nutrients and energy which <u>are</u> either

and] for feeding older infants and young children as a complement [supplemented complement] supplement to breastmilk or breastmilk substitutes to provide those nutrients and energy which either are lacking or are present in insufficient quantities in local diets. These foods include foods such as porridges, ready-to-use-products (pastes and compressed bars), and a food-based home fortificants to enrich [fortify] other foods available in the country where the product is sold or otherwise made available. They are not suitable for use for infants before six months of age. the beginning of the weaning period. These foods provide those nutrients which either are lacking or are present in insufficient quantities in the local diets basic staple foods. They are not suitable for use by infants under six months of age.	lacking or present in insufficient quantities in local diets' basic staple foods.. These foods include porridges, ready-to-use pastes and <u>soft</u> compressed bars, and a food-based home fortificants (<i>note: assuming that the words "home food-based fortificants" are well defined and accepted by the Committee</i>) to enrich other foods available in the country where the product is sold or otherwise made available. <u>These</u> foods are not suitable for use by infants under six months of age.
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Justification: For consistency with WHO definition of complementary foods to wit "solid to semi-solid foods given to older infants (6 months to less than 12 months) and young children (12 to 36 months of age) in addition to breastmilk or breast milk substitutes" (as contained in Alinorm 10/33/26 para 110), the phrase "as a complement supplement" is changed to "in addition to." Editorial corrections were made by moving the word "are" before the word "either." While the succeeding words "are" and "those" before the words "present" and "nutrients" respectively, are also deleted. Redundant sentences are likewise deleted. The word "they" (which may refer to persons) in the last sentence was changed to "These" (which refer to things/objects). While the word "soft" is added before the words "compressed bars" to ensure the guidelines refer to compressed bars which are chewable by older infants and young children. For clarity, the words "food-based home fortificants" has to be defined in terms of composition and quantity.

From	To
3.4 The term <i>Complementary feeding period</i> means the period when older infants and young children transition from exclusive feeding of breast milk feeding and/or breast milk substitutes to eating the normal family diet. (i.e. children from 6 months of age to 36 months of age).	3.4 The term <i>Complementary feeding period</i> means the period when older infants and young children transitions from exclusive feeding of breast milk feeding and/or breast milk substitutes to eating the normal family diet.

Justification: Editorial editing was made to add letter "s" in the word "transition."

On item 3.5, the revised draft guidelines meaning of "Food-based home fortificants" and additional micronutrients should be well defined to avoid inappropriate fortification as this may imply that fortification can be left in the hands of the consumers. Fat soluble micronutrients (such as vitamins A, D, E and K) when taken in excess may pose risk to health. Hence, for clarity, the terms "Food-based home fortificant" has to be defined in terms of composition (ingredients) and quantity including the mentioned additional micronutrients and the method of preparations.

5. Suitable Raw Materials and Ingredients

From	To
4.2.1. [Animal Source Foods Animal source foods such as meat, fish, poultry and eggs are nutrient dense foods and should be promoted during the complementary feeding period.]	4.2.1 Animal source foods Nutrient dense foods form animal source such as meat, fish, poultry and eggs may be added during the complementary feeding period.

Justification: The phrase “and should be promoted” may be deleted as the word “promoted” is inappropriate in this sentence. The phrase may be replaced by “may be added” to simplify the sentence.

The Philippines further supports the removal of square brackets under items 5.5.2.1 and 9.2.3 (b). Item no. 9.2.4.4, the Electronic Working Group may have been evaluated pertinent information contained in this draft and may need to include in this item what they consider “an appropriate essential fatty acid ratio” for clarity.

SOUTH AFRICA

South Africa supports the Proposed Draft Revision of the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 08-1991 at Step 4), prepared by the electronic working group chaired by Ghana, with a number of suggestions for consideration and discussion, as follows:

1. GUIDELINES ON [SPECIFICALLY] FORMULATED [FORTIFIED] COMPLEMENTARY (SUPPLEMENTARY) [COMPLEMENTARY SUPPLEMENTED] FOODS FOR OLDER INFANTS AND YOUNG CHILDREN (CAC/GL 08-1991)

Comment: South Africa does not support use of the term “Complementary” but rather prefers the term “Supplementary” for this document, because of the definition given for complementary in section 3.4. These guidelines pertain to formulated foods for older infants and young children who cannot meet their nutritional requirements from the locally available diet.

How do we know that nutritional requirements are not met? Is it by the use of Food Diaries or 24 hour recall to measure intakes? Underweight measure is the most used indicator for action to inadequate nutritional intake. South Africa needs clarity because according to our understanding the targets for these guidelines are basically at risk of being malnourished.

2. Description

3.4 Suggestion to add to the description of Complementary feeding to read as follows for Codex purposes: “Complementary feeding period means the period when older infants and young children transition from exclusive feeding of breast milk feeding and/or breastmilk substitutes to eating the normal family diet *with breastfeeding to two years and beyond.*”

3. 3.5 “Food-based home fortificant means a food that contains high quality protein and additional micronutrients for the purpose of mixing with local foods at the time of consumption to increase nutrient and energy intake.”

Comment: These are foods for prevention and treatment of those at risk malnutrition. For the treatment of severe acute malnutrition these foods should be used when medically indicated and not marketed as routine complementary foods but rather as supplements for prevention and treatment of malnutrition.

4. 4.1.2 Pulses

Comment: South Africa suggests that the pulses should not be listed as they exclude other pulses but should only be referred to as “suitable pulses”, or alternatively all the possible types of pulses should

all be listed. Certain good pulses such as butter beans, small white beans, etc are excluded in the current wording.

5. 4.2.1 [Animal Source Foods]

We suggest that under 4.1.4, in a category of animal-derived foods, red meat such as liver, rich in iron, is also allowed and given as an example.

6. 5.2 Milling

Comment: In addition to milling, the information also covers boiling, and the heading should be Milling and boiling.

Point 5.2.3. Also mention that boiling could reduce some of the vitamins in the food.

7. Point 6.2.3.

Comment: Express energy in both kilocalories and kilojoules and indicate more clearly, using an example, of the minimum energy contribution of a reconstituted serving. (The following point was raised by some members of the group who were concerned about the double burden of both under and over nutrition: Should one consider also a maximum energy contribution per serving, or will the guidelines regarding protein and carbohydrate with a limitation of fat content be sufficient to ensure the prevention of "overfeeding" and obesity?)

8. Addition of wording: 6.3.3 If, for technical reasons, the PDCAAS of a protein cannot be determined, the protein quality should be measured by biological assays *taking the processing methods into account*. Alternatively, the protein quality may be computed from published data on essential amino acid patterns of dietary proteins and their digestibility.

9. The use of terminology should be harmonized with other Codex documents.

For example, Point 6.6.4: RNIs, are they INL₉₈?, although Estimated Average Requirements are actually Average Nutrient Requirements or ANR (see Food and Nutrition Bulletin, Vol 28, number 1, March 2007, supplement on International harmonization of Approaches for Developing Nutrient-Based Dietary Standards, p. 11). Similarly, is the term in the first Table (Annex) INL₉₈? and in the second one ANR?

10. Zinc needs a superscript in the first Table to explain the 3 values given (as done in the second Table).

11. 7.2 When tested by appropriate methods of sampling and examination, the product:

(a) shall be free from pathogenic microorganisms

Comment: This statement should be in line with Codex standard for powdered milk infant formula minimum levels or this Guideline would be stricter than this standard for older infants and young children.

UNITED STATES OF AMERICA

I. General Comments

The United States thanks Ghana for leading the Electronic Working Group and for preparing a revised draft of these guidelines for the Committee's consideration. We offer the following preliminary comments, and anticipate providing additional comments at the upcoming session.

Name of Product Category

There continues to be confusion and difference of opinion in the comments concerning the name of the product(s) covered by these guidelines. Three characteristics seem to distinguish this category of foods: formulated, fortified, and complementary. However, names that incorporate all three

components are cumbersome and we believe the more concise descriptor “Fortified Complementary Foods” can be used to capture the characteristics of this product category. For the reasons explained in the following paragraphs, we propose “Guidelines on Fortified Complementary Foods for Older Infants and Young Children” as the title for the revised document and use of the term “fortified complementary foods” as the product name in the guidelines document.

We suggest the term “fortified” because it provides an accurate description of foods to which nutrients are added. Use of the term “supplement” or “supplemented,” would be confusing because it is used to mean something different from its use with regard to dietary supplements. Use of the term “supplementary” would target the use of these foods for moderately malnourished children per the definition of supplementary foods provided by WHO: “Supplementary foods are formulated foods used to rehabilitate moderately malnourished children or persons, to prevent a deterioration of nutritional status of those at risk by meeting their additional needs”. As these foods would be for all children and would be used to prevent children from reaching a malnourished state, use of the term “supplementary” is also not appropriate.

All the foods covered by this guidance are products formulated from multiple ingredients. This could be made clear by incorporating the word “formulated” into the statement of purpose. This change would make it unnecessary to use the word “formulated” in the name of the product category. We suggest the following edit to the statement of purpose:

I. Purpose

To provide guidance on nutritional and technical aspects of the production of ~~[specifically] formulated~~ **fortified** complementary ~~supplementary~~ ~~[complementary-supplemented]~~ foods **formulated** 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.

II. Specific Comments

4.2.1 Animal Source Foods

Comment: If this section is added, it should be edited to clarify use of animal source foods. We suggest the following edits.

4.2.1 Animal source foods such as meat, fish, poultry and eggs are ~~nutrient dense foods and should be promoted~~ **sources of complete proteins and can be included in the diets of older infants and young children** during the complementary feeding period.”

4.2.2 Digestible carbohydrates including sugars

Comment: The statement “Provide less than 10% of the total energy of the product” has been added to “digestible carbohydrates including sugars” but it not highlighted as a new addition. The recommendation in the reference cited (WHO TRS 916) was made in the context of the total diet and was not intended to pertain to individual foods. We question why this recommendation is applied to individual foods in this Proposed Draft Revision.

6.6 Vitamins and Minerals

The principles in section 6.6 for the addition of vitamins and minerals to fortified complementary foods will provide valuable assistance for the users of this guidance.

The principles in section 6.6 are largely consistent with the definition of the product in section 3.1, which states “These foods provide those nutrients which either are lacking or present in insufficient quantities in the local diets.” For example, the principle in section 6.6.1 states “The addition of vitamins and minerals should take into account local nutrition and health conditions as well as the requirements stipulated by national legislation.” However, section 6.6.4 does not appear to be consistent with the this product description in Section 3.1, as Section 6.6.4 refers to the Annex Table, which provides a single set of values (whether a percentage of the Reference Nutrient Intakes or the

Estimated Average Requirements). The Annex Table presents the values in the context that the daily ration of the food should contain at least 50% of the RNI for vitamins and minerals that are added, which does not appear to be consistent with the desired approach of formulating these products to fit the needs of infants and young children living in particular localities as a part of their entire diet. We would like clarification on this apparent inconsistency.

An alternative approach to providing guidance on addition of vitamins and minerals that is linked to a fixed percentage of the RNI or other single set of values, with the implication that these values are appropriate for use in all situations, could be to revise 6.6.4 to incorporate concepts currently presented in the introductory paragraph in the Annex.

6.6.4 Local conditions including the nutrient contribution to the diet from local foods 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. Complementary fortified foods should be formulated to 1) contain sufficient amounts of vitamins and minerals to meet the daily requirements when consumed with the foods in the local diet and 2) not result in excessive intakes when consumed in combination with other foods in the local diet and any vitamin and mineral supplements that are provided separately.

A provision (6.6.5) should also be added to the guidelines, stating that recommendations from FAO/WHO should be used as the source of information about the daily requirements of vitamins and minerals for older infants and young children. Such a provision would guide the reader to the FAO/WHO recommendations and reduce the need to update these guidelines because of revisions in nutrient intake recommendations. With this approach, the Annex text and table could be removed from the guidelines. We suggest the following language for this provision:

6.6.5 Current recommendations from FAO/WHO should be used as the source of information about the daily requirements of vitamins and minerals for older infants and young children.

The United States appreciates the opportunity to share these preliminary comments, and looks forward to providing additional comments at the upcoming session.

WFP – World Food Programme – Part I

1) The fact that the 1979 hygiene guidelines have been removed from the Codex website means that there is currently only the infant formula guidelines that can be referred to when seeking to set standards for microbiological contamination (i.e. Mesophylic aerobes, coliforms, salmonella and possibly *B. cereus*) in to-be-cooked as well as for ready-to-use products for young children. It is therefore important that the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children specifies those standards for both types of products (to be cooked & ready to use).

2) It would be very good if a maximum for Aflatoxin could also be specified.

WFP – World Food Programme – Part II

Page 3. The discussion about complementary vs supplementary is well summarised in the comments but terms such as ‘complementary supplemented’ will cause total confusion. If necessary the two WHO definitions should be included in the introduction.

3.1 In many developing country situations these products are used as both replacements for and complements to breast milk for children above 6 months of age.

3.5 *Home fortificant* – an unusual term. Also why remove ‘and fat’. Most animal and plant proteins

are associated with fat in their natural state.

4.1 *Ingredients* . No mention of tuber starches. If these are not recommended (e.g, viscosity characteristics) reasons should be stated.

4.1.2.3 *Phytates can be reduced enzymically by soaking or fermentation*. This implies that microbial phytases are appropriate. ‘Soaking’ should probably be replaced by ‘germination’.

4.1.3.1 Full fat groundnut or sesame will form pastes and not flours when milled.

4.1.4.1 *Care must be taken.... affect, nutrition, flavour AND SHELF LIFE*.

4.1.5.1 *The minimum requirements for essential fatty acids should be met* (as given in 6.4.7)

4.1.6.1 **Milk / dairy products**. What is the position on milk fat? The implication is that full fat milk/powder is undesirable. A reason should be given if milk fat should be reduced.

4.2.2 *Nutritive sweeteners* needs defining. Do Nutriset products contain less than 10% sugar, whether as sucrose, dextrose, lactose ?

5.1.2 *Dehulling.... to reduce the crude fibre to acceptable levels* - but 6.5.2 refers to dietary fibre. Which is to be used?

5.1.2 *and if possible to eliminate phytates etc.* – Preferable to set an upper limit for phytates (including recommended test method).

5.1.3 *Degermination should be considered to reduce phytates* – while recognising that losses of protein, essential fatty acids, vitamins and minerals in the germ should be compensated within the product formulation.

5.3.3 *Toasting*. Soya is commercially toasted after solvent de-fatting.

5.5.2.2 Replace ‘feed’ with ‘food’

6.1.2 Grammes or Grams? Fifty grams as an upper limit for CSB is rather low.

6.1.5 *..Care.. do not regularly exceed relevant upper nutrient levels*. Which are? Ref needed.

6.3.2 *PDCAAS* remains contentious due to the highly variable values given for the same protein. Codex should give references or publish a list of scores. In the footnotes, casein should be stated as the reference protein.

6.5.2 *Dietary fibre* – the method of analysis should be indicated.

9.2.3 *Declaration of nutritive value* – grammes or grams?

Annex pg 12. A reference should be given for the typical vitamin and mineral content in human breast milk.

Comments and responses section: This section presents a number of valuable rationales upon which limits or nutrient intakes etc are based. These should be included in a technical annex otherwise queries will continue to arise when the guidelines are finalised. The basis upon which the guidelines are made are as important as the guidelines themselves.

IBFAN – International Baby Food Action Network

IBFAN wished to thanks Ghana for chairing the EWG to develop the draft guidelines and for the opportunity to comment on the proposed revision of the guidelines on Formulated Supplementary Foods for Older Infants and Young Children CAC/GL 08-1991

IBFAN wishes to make the following general comments regarding this proposed work.

1. The proposed work needs to clearly establish how the revision of FSFs will improve the nutritional status of older infants from the 7th month of age and young children to the age of 36 months.
2. IBFAN is concerned that the proposed guidelines will increase the need for regulation, monitoring of marketing practices and impact on nutritional status and health outcomes as well as enforcement on the part of governments where resources are scarce. Ferguson and Darmon, in their analysis of traditional versus fortified foods, note that the use of fortified foods is not advised “where there is an absence of effective governmental regulatory infrastructures”.
 - i. Ferguson EL, Darmon N. Traditional vs. Manufactures Baby Foods. In Agostini C, Brunser O. Eds. Issues in Complementary Feeding. Nestle Nutrition Workshop series. Pediatric Program, Vol 60

3. The proposed draft revised guidelines do not need to differ significantly from the standard for processed cereal-based foods for infants and young children (CODEX STAN 074-1981 Rev. 1-2006). Additionally a standard is more binding than mere guidelines. Foods for older infants and young children need rigorous and enforceable standards to protect against inappropriate use, chemical contaminants, inferior quality, and microbiological contamination.
4. A wide range of core ingredients ranging from cereal grains, starchy roots, pulses and milks and a full complement of vitamins and minerals for the purpose of fortification of these products is permitted for CODEX STAN 074-1981 Rev. 1-2006. The levels of added nutrients permitted can easily meet the nutrient density levels required to meet the needs of all older infants and young children.
5. Similarly recommended serving sizes can readily be addressed through the labeling provisions of the standard for processed cereal-based foods (CODEX STAN 074-1981 Rev. 1-2006).
6. IBFAN is also concerned about the impact on consumer decision making – will these additional guidelines create confusion in the market place? Will these guidelines distort parents understanding of good nutrition and affect taste palettes, and, lead to an increase in the double burden of malnutrition – both over and under nutrition. The increased availability of commercial fortified complementary foods for infants and young children for various “uses” is already creating considerable confusion for parents, care givers and health care providers. How will parents be able to differentiate between products marketed under the proposed guidelines and those falling under the current standard for cereal-based foods.
7. The availability of increased commercial fortified complementary food products in the market place can result in the competition of these foods with the recommended duration of sustained breastfeeding from 6 to 24 months. Although the introduction of complementary foods is recommended after the age of six months, breastmilk remains the most important food, providing optimal micronutrients, immunology, and meets an infant’s protein needs for the first 12 months of life. Additionally breastfeeding provides important child spacing and psychological stimulation critical for cognitive development. These important health and developmental outcomes cannot be replicated in fortified complementary foods, while the benefits of the fortified food products are frequently overrated. Limiting the number of products available and marketed for 6 to 36 months reduces the risk of breastmilk replacement.
8. The marketing and labeling of all complementary feeding products needs to be in full conformity with the *International Code of Marketing of Breast-milk Substitutes and subsequent relevant WHA resolutions* to ensure that inappropriate marketing is controlled and that breastfeeding practices and the use of energy dense and high nutrient local, culturally appropriate foods are protected. There should in any case be no health or nutrition claims or any idealizing pictures or text permitted on these products. They should also include a clear recommendation regarding the importance of continued breastfeeding to two years and beyond, after exclusive breastfeeding for the first six months, and very clear instructions to ensure that the product is not used at too early an age or used inappropriately (i.e. in a bottle)
9. To reduce the problems of confusion and overlap for both regulators and parents, IBFAN recommends that a “Part C” (similarly to what is being proposed by India “Part B”) or an Annex to CODEX STAN 074-1981 Rev. 1-2006 for processed complementary foods as the way forward. A “Part C” can accommodate the ingredient and micronutrient variations required to meet a wider scope of specific needs for the feeding of older infants and young children as expressed by the Ghana proposal.
10. Independently funded research into the efficacy of fortified complementary foods as compared to optimal breastfeeding practices and the use of nutrient rich and energy dense local, culturally appropriate foods is needed to determine if there are growth and developmental benefits to the feeding of fortified commercial complementary food products at these vulnerable ages. Until such

research is available and clearly confirms an important role these foods with no unintended and unacceptable consequences, older infants and young children should not be subject to mass feeding trials.

11. It has been demonstrated that interventions to ensure optimal nutritional status and prevent under nutrition can be achieved by improving breastfeeding rates and the use of indigenous energy dense and nutrient rich complementary foods. Optimal feeding, combined with nutrition education and primary health such as the elimination of parasites and the treatment and prevention of malaria are the most effective and least costly in improving nutritional status and child health. The use of costly, commercial fortified products is not sustainable and uses scarce resources in resource poor situations. Previous attempts to improve young child nutritional status and prevent under nutrition with fortified commercially manufactured “mixes” have not been successful.
 1. Black R E et al. Maternal and Child undernutrition. Global and regional exposures and health consequences. Lancet 2008; 371: 243-60
 2. Lauer JA et al. Deaths and years of life lost due to suboptimal breast-feeding among children in the developing world: a global ecological risk assessment. Public Health Nutrition, 2006; 9(6):673–685
 3. WHO. Indicators for Assessing Infant And Young Child Feeding Practices for peer review. Conclusions of a consensus meeting held 6-8 November 2007 in Washington D.C.
12. Undernutrition and malnutrition is highest in the poorest countries of the world, where national legislation to monitor the importation, nutritional and hygienic quality, the labeling and the marketing and importantly the use of these products may be very difficult. Scarce trained human resources and financial capacity to administer the safety and use of these products may seriously compromise national capacity for more effective and sustainable means to address nutrition needs for older infants and young children. Global experts are beginning to question the wisdom of using a “magic bullet” approach.

(Sachs J, Fanzo J, Sachs S (2010). Saying nuts to hunger. Huffington Post, Sept 6.
http://www.huffingtonpost.com/jeffrey-sachs/saving-nuts-to-hunger_b_706798.html)
13. Infants who are breastfed for the recommended time have fewer micronutrient deficiencies, suffer fewer respiratory and diarrhoeal diseases and are at much lower risk of malnutrition. This is not just a result of exclusive breastfeeding up to 6 months, but the fact that breastmilk can provide about half an infant’s energy needs between 6 and 12 months, and one-third of energy needs between 12 and 24 months, as well as a high proportion of their Vitamins A and C needs and 50% of iron.

ISDI - International Special Dietary Foods Industries

ISDI wishes to thank Ghana for chairing the electronic working group and preparing the draft document on the new work to revise the “Codex Guidelines on Formulated Supplementary Foods for Older Infants and Young Children”, and the Codex Secretariat to give us another opportunity to share some of our comments.

GENERAL COMMENTS

ISDI considers that one essential element is a good definition of the categories of products considered, and of the infant and young children to whom these products are intended, in order to avoid overlaps and confusion with current standards.

On a general basis, ISDI considers that the revision of the guideline should be an opportunity to clarify it, reviewing if necessary the structure of the text. It is essential for this Guideline, as opposed to Standards, to be as general as possible and cover the whole category, i.e. foods and foods fortificant.

You will find in the table below the different comments of ISDI.

GUIDELINES ON SPECIFICALLY FORMULATED SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN (CAC/GL 08-1991)

ISDI proposed amendments	Rationale
<p>2. SCOPE</p> <p>The provisions of these Guidelines apply to [specifically] Formulated [fortified] Complementary Supplementary [complementary supplemented] Foods for Older Infants and Young Children as defined in Section 3.1 below. <i>The existing Codex standards and Guidelines, including the standards that apply to infant and follow-on formulae, processed cereal based foods and canned foods designed for infants and young children are out of the scope of these guidelines. Micronutrient powders are not covered by this Guideline.</i></p>	<p>In order to avoid overlaps and confusion with current standards, ISDI considers essential to clarify that <i>the existing Codex standards and Guidelines, including the standards that apply to follow-on formulae (CODEX STAN 156 1987), to infant formula and formulas for special medical purposes intended for infants (CODEX STAN 72 1981 rev 2007), to Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74 1981 rev 2007) and to Canned Baby Foods, processed cereal based foods and canned foods designed for infants and young children (CODEX STAN 73 1981) are out of the scope of these guidelines.</i></p>
<p>3.1. [Specifically] Formulated [fortified] Complementary [Complementary Supplemented] Foods for Older Infants and Young Children means foods that are suitable [for feeding older infants and young children as a complement[supplemented complement] to breastmilk or breastmilk substitutes <i>or other food available in the country</i> to provide those nutrients and energy which either are lacking or are present in insufficient quantities in local diets. These foods include s, ready-to-use- <i>products</i> and a food-based home fortificants or They are not suitable for use by infants under six months of age.</p>	<p>ISDI considers that these guidelines are not only targeting young children having breastmilk or breastmilk substitutes. These guidelines target all young children population having specific needs.</p> <p>As these guidelines apply to a wide variety of foods, it has to remain as generic as possible to be broadly implemented. As a consequence, ISDI is not in favour of mentioning examples of foods in this paragraph such as porridges, pastes, bars. In the version 2 proposed by Ghana for point 3.1, some inputs of countries were not fully taken into account.</p>
<p>3.5: The term food-based home fortificant <i>is a category of</i></p> <p>3.1 and means a food <i>fortificant that could be used to enrich homemade food either with macro nutrient or with micronutrients which are partly lacking in the diet. These products are used for fortification of foods available in the country where the fortificant is sold. They are added at the time of preparation to provide specified amounts of nutrients. Non food supplements such as micronutrients powders should be addressed</i></p>	<p>ISDI considers essential to better define the term food-based home fortificant, in order to avoid confusion.</p>

<i>separately.</i>	
4. SUITABLE RAW MATERIALS AND INGREDIENTS 4.1 Basic Ingredients The following raw materials, most of which are locally available, are suitable ingredients for the production of <i>specifically</i> formulated supplementary complementary foods for older infants and young children under the specified conditions given below:	ISDI favours the deletion of the square brackets around “specifically”.
4.1.1.2 Besides carbohydrates (mainly consisting of starch) cereals contain a significant quantity of protein (8-12%). Whereas rice has a satisfactory essential amino-acid composition, However, all other cereals are as a rule limiting limiting in lysine. <i>Combining cereals with other plant foods (e.g. pulses) can compensate for limiting amino acids.</i>	ISDI favours this introduction in order to add some flexibility, and take into account the reality of local diets.
4.1.2.1 Pulses, including chick peas, lentils, peas, cow peas, mungo beans, green gram and kidney beans, <i>soya, etc., contain</i> are a good source of appropriate proteins (20-24-35%) protein.	ISDI favours the addition of soya, among other potential examples, in order to better recognize the place of the ingredient.
4.1.4.1 Food quality meals from edible fish species and edible fish protein concentrates are acceptable if produced under appropriate conditions³. Care must be taken to avoid oxidized fat which will adversely affect nutrition and flavour.	On 4.1.4.1, ISDI questions the fact to have the specific request for this particular ingredient. The quality of ingredients should be addressed in the chapter 5.
4.1.5 Fats and Oils 4.1.5.1 Fats and oils should be added to the preparation if possible for the purpose of increasing the energy density of the product. 4.1.5.2 The minimum requirements for essential fatty acids should be met. 4.1.5.3 Partially hydrogenated oils containing (trans) fatty acids should not be used in formulated complementary [complementary supplemented] foods ³ for older infants and young children (Codex STAN 074 1981, Rev. 1-2006) <i>Fats and oils have to be appropriately processed to reduce, as far as possible, the Trans fatty acids content.</i>	Regarding Fats in general, ISDI would oppose the general setting of a minimum limit for fat, as this should be justified on the basis of the local diet and decided at national level according to local context. ISDI would like to stress that PAHO/WHO recommendation is for the <u>diet</u> and not for a specific product. ISDI wonders if this criteria is a relevant one in that perspective, especially since they are products requiring addition of oil at the point of use (as foreseen in point 9.2.4.4 and 9.2.4.6) that would not comply. On 4.1.5.3, ISDI considers that there is no evidence that Trans fatty acids from hydrogenated fats is different to that of naturally occurring Trans fatty acids in milk or meat fat. There is therefore a need for consideration for the proposed prohibition.

<p>4.1.6 Milk and/or milk products</p> <p>4.1.6.1 Dairy Milk and milk products are nutrient dense and good sources of high quality proteins and other micronutrients. They and are considered beneficial to growth and can be added to complementary food. Dairy products They can be added as dried skimmed milk, full fat milk and semi-skimmed milk solids</p> <p>Whey proteins concentrates are a readily available source of protein with a high bioavailability which can be used to increase and improve the protein level of formulated complementary foods</p>	<p>ISDI would favour the deletion of specific references that could create confusion, such as direct references to whey, when the example (whey) is already covered by previous paragraph but does not encompass all the examples (e.g. casein and so forth)</p>
<p>4.2.2 Digestible carbohydrates including sugars</p> <p>Energy density should preferably be increased by the addition of fat and/or digestible carbohydrates. If nutritive sweeteners are used, they should be used in moderation. provide less than 10% of the total energy of the product.</p>	<p>ISDI considers that “The recommendation in the reference cited (WHO TRS 916) was made in the context of the total diet and was not intended to pertain to individual foods. We question why this recommendation is applied to individual foods in this Consultation Document”</p> <p>ISDI supports that the formulation is done on a case-by-case basis in line with the scope of the Guidelines “The formulation is specifically providing the nutrients which either are lacking or are present in insufficient quantities in local daily diet”</p>
<p>4.2.3 Flavours: Ethylvanillin and vanillin (7 mg/100g RTU), natural fruit and vanilla extract, <i>vanilla and/or traditional flavours</i> may be used provided they have been evaluated for their safety-in-use.</p>	<p>ISDI would favour the extension of the scope of flavours to vanilla and traditional flavours in order to cover all potential situations in local diets (e.g. vegetable extracts) and the reality of the multiplicity of products that can be covered by these guidelines. It is also understood that the use is only authorised provided the flavours have been evaluated for their safety-in-use.</p>
<p>5.5.1.2 The effects of this technology are:</p> <ul style="list-style-type: none"> • 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. • <i>flavour development</i> 	
<p>5.5.2 Enzymatic Predigestion</p> <p>5.5.2.1 Under this process the milled or ground basic ingredients (cereals, pulses, oilseed flours) are [processed in the presence of water and appropriate enzymes]</p>	

<p>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.</p> <p>5.5.2.2 The predigested product has improved organoleptic characteristics, higher digestibility, good solubility and requires less water for the preparation of the feed (higher nutrient density).</p>	
<p>6.1.2 Ten to fifty One hundred grammes of the product, or any other relevant volume as needed, when prepared according to the instructions, is considered a reasonable quantity which an older infant or young child fed breast milk can ingest easily in two or more feedings per day. This range provides an allowance for the various types of [fortified 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 applies to products with lower energy density (e.g., cereal-based products)</p>	<p>ISDI would introduce the suggested changes in order to ensure flexibility and that the definition can allow the meeting of the specific requirements or realities of local diets.</p>
<p>6.1.3 The selection of ingredients for the formulation of specifically Formulated Complementary Supplementary [complementary supplemented] Foods to supplement the local diet of 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:</p> <ul style="list-style-type: none"> * nutrient content of the local diet (including breast milk) (including processed cereal-based foods and canned baby foods when relevant) * amount and 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. 	<p>ISDI would favour the deletion of references to cost, as the question here is mainly a nutritional one, which should disregard at that stage any specific reference to economic.</p>
<p>6.1.5 combined total amounts of the complementary food micronutrient fortification, daily micronutrient intake micronutrients that may be provided separately should not regularly exceed the recommended dosage relevant upper levels of micronutrient result in excessive intake for older infants and young children, except when necessary to compensate for deficiency and/or favour micronutrients reserves in the body.</p>	<p>ISDI considers the following changes are necessary in order to give flexibility and the potential to adapt to specific local conditions.</p>
	<p>ISDI would propose the following</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 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>changes, to put in place of provisions 6.3.2 and 6.3.3, the more as these provisions may be a burden for developing countries</p>
<p>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 computed from published data on essential amino acid patterns of dietary proteins and their digestibility.</p>	<p>ISDI would suggest the deletion of 6.3.3 in line with the comment on 6.3.2.</p>
<p>6.3.5 Taking into account the preceding considerations, the energy from protein⁸ content should not be less than 10% of the total energy from the product⁹. be in the order of 15 g per 100 g of the food on a dry matter basis⁶</p>	<p>ISDI supports the deletion of this paragraph in order to give flexibility and have guidelines adapted to any local situation.</p>
<p>6.4 Fat</p> <p>6.4.1 Incorporation of adequate quantities of fats and/or oils, as technologically feasible, is recommended in order to increase the energy density, increase the amount of essential fatty acids and reduce total volume 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 fat⁸ would be desirable⁹. This corresponds to between about 10 g and 25 g of fats and/or oils in 100 g of the food.</p>	<p>ISDI supports the deletion of this sentence in order to give flexibility and have guidelines adapted to any local situation.</p>
<p>6.4.2 <i>When adequate for the product (or “when relevant for the aim of the product in the diet,</i> The level of linoleic acid (in the form of glycerides) should not be less than 300 mg per 100 kcal or 1.4 g per 100 g of dry product and the ratio between linoleic acid and alpha-linolenic acid should be between 5:1 and 15:1.</p>	
<p>6.5.2 Increasing the intake of dietary fibres¹⁰ increases enhances stool bulk, may cause flatulence and decrease appetite. They also may Fibre load also can affect the efficiency of absorption of important various nutrients of significance from in diets with a marginal nutrient contents. so The dietary fibre content of the [formulated] [fortified complementary] food should therefore be reduced to a level not exceeding 5 g per 100 g on a dry weight basis.</p>	<p>ISDI would favour the deletion of that sentence in order to give flexibility and have guidelines adapted to any local diets.</p> <p>In that specific case not all fibres inhibit the absorption of vitamins and minerals, and there is no distinction between soluble and insoluble dietary fibres.</p> <p>In addition the footnotes on this page do not match with those in CX/NFSDU 10/32/6 of September 2010.</p>

	<p>Footnote 10 (on page 9 in CX/NFSDU 10/32/6) in relation to item 6.5.2 apparently has to do with the definition of dietary fibre and not with flatulence etc.</p> <p>On setting a maximum level, the following comment taken from the 2006 report of the Health Council of The Netherlands on guidelines for dietary fibre intake:</p> <p>Tolerable upper intake level</p> <p><i>According to the Institute of Medicine, there is insufficient data available to set a tolerable upper intake level. A high intake of dietary fibre may reduce the bioavailability of minerals owing to the presence of phytate in high-fibre products. However, this effect is to a great extent offset by the usually high mineral content of the concerned products. A high intake of dietary fibre may also cause intestinal complaints, such as flatulence, gas formation and diarrhoea. However, these complaints are rarely, if ever, serious. Moreover, the consumption of high-fibre foods is self-limiting owing to their voluminous character. The effects on mineral bioavailability and intestinal complaints might well be a problem if a high fibre intake is achieved by the use of fibre supplements. Owing to these considerations, the Committee endorses the Institute of Medicine's decision not to set a tolerable upper intake level.</i></p>
<p>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 formulated complementary [complementary supplemented] food.</p> <p><i>The addition of vitamin and minerals and the nutrients to be considered in the development of a complementary and supplementary food for older infants and young children should also take into account the WHO/FAO Guidelines on food fortification with micronutrients (2006), the Codex guidelines on nutrition labelling and the future Codex principles in the development of NRVs</i></p>	<p>ISDI suggests that the Nutrient Reference Values for older infants and young children are not in the scope of this guidelines but discussed as part of the “Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Codex Guidelines on Nutrition Labelling” (ALINORM10/33/26 - Appendix IV), which is currently discussed at CCNFSDU.</p> <p>ISDI considers that in having NRV detailed in specific guidelines, revision of the guidelines occurs when revision of the NRVs occur, which is not an adequate process.</p>

ISDI would therefore favour the deletion of section 6.6.4 and of the table of RNIs in the Annex, considering that those elements shall be developed in relation with NRVs by a specific working group in Codex, and that this table would be detrimental to the flexibility that is needed by national authorities to face specific contexts in relation with the formulated supplementary foods for older infants and young children.

Two options to consider with regard to the inclusion of a Table in the Annex:

1. Again ISDI reiterates that the specific values in the Table be based on new work on the Nutrient Reference Values for older infants and young children that is anticipated to be discussed as part of the “Proposed Draft Additional or Revised Nutrient Reference Values for Labeling Purposes in the Codex Guidelines on Nutrition Labelling (Alinorm 10/33/26-Appendix IV) which is currently under discussion at CCNSFDU.

OR

2. Alternatively, ISDI could concur with US and Mexico, with support of the use general principles for establishing nutrient levels to be added to the FCF instead of prescriptive values based on RNI or EAR. Reference could be made to Committee on Nutrition and Foods for Special Dietary Uses’ proposed general principles for establishing Nutrient Reference Values of Vitamins and Minerals for the General Population as a draft annex to the Codex Guidelines on Nutrition Labelling. (See Appendix III of ALINORM 10/33/26).

In any case, ISDI recommends that the text be revised so that it is clear that the Table in the Annex provides the reference nutrient intakes for those vitamins and minerals for which levels

	have been established, and not only those most frequently deficient.
7.3. The product shall be prepared, packed and held under sanitary conditions and should comply with relevant codex text(s) ¹¹ <i>depending on the type of specifically formulated complementary foods.</i>	ISDI considers that the word “relevant” has to be explained and suggests this addition as clarification.
9.1 It is recommended that the labelling of <i>Specifically Formulated Supplementary</i> 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). <i>“Taking into account paragraph 1.4 of the Guidelines for Use of Nutrition and Health Claims, nutrition claims may be permitted under national legislation for the foods that are the subject of the standard provided that they have been demonstrated in rigorous studies with adequate scientific standards”.</i>	ISDI would support the inclusion of additional text to section 9.1, to allow communication on the aim of the products intended for specific nutritional purpose, based on scientifically supported nutrition and health claims, in language similar to that in the Section 8.1 of the Codex Standard for Processed Cereal Based Foods for Infants and Young Children STAN 074-1981, REV. 1-2006:
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 should be given when nutritional requirements of older infants and young children are not met by locally available foods FOOTNOTE during the complementary feeding period but not before the 6th months of age. and when nutritional requirements are not covered by locally available foods. (c) a statement that the food should not be fed to infants under 6 months of age.	ISDI believes that a footnote such as “* <i>locally available food includes homemade food as well as processed cereal-based foods (STAN 47-1981 rev 1-2006) and canned baby foods (STAN 73-1981)</i> ” would clarify the text.
9.2.3 Declaration of Nutritive Value The declaration of energy and nutrients on the label or in labeling shall contain the following information expressed per 100 grammes of the food as sold or otherwise 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, expressed in kilocalories and kilojoules; (b) the amounts of protein, carbohydrates and fat, [and the amount of linoleic and alpha-linolenic Acid <i>when relevant</i>], expressed in grammes or [milligrammes] where appropriate. (c) in addition to any other nutritional information required by national legislation, the total quantity per feeding of in the food as sold or in the final	

<p>product ready for consumption of each vitamin and mineral added in accordance with Section 6.6 expressed in metric units.</p>	
<p>ANNEX</p> <p>TABLE</p> <p>The 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 should be considered in the formulation of a complementary supplementary food.</p> <p>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, the total amount quantity of the each of these added vitamin(s) and/or mineral(s) contained in a per daily ration in 100 g of the food on a dry matter basis should be at least 50% 2/3 of the reference nutrient intake. daily requirements. scientifically determined taking into account the nutrient contribution of breastmilk as well as local conditions including the nutrient contribution to the diet from local food and the nutritional status of the target.</p>	<p>ISDI underlines the need to assess the Annex regarding WHO work, which is on-going.</p> <p>ISDI favours reference to national nutritional references and stresses the necessity of providing general principles for establishing nutrient levels to be added to the FCF instead of prescriptive values based on RNI or EAR.</p> <p>ISDI does not support a single reference value of 50% for the amount of nutrients that should be contained in a daily ration. The amount should be scientifically based considering local conditions including the nutrient contribution to the diet from local food and the nutritional status of the target population as well as nutrient contribution of breast milk and national legislation.</p> <p>ISDI also questions the wording in the last sentence as it implies that an enriched/fortified complementary food should be enriched/fortified with all nutrients listed in the table. The text needs to be revised.</p> <p>ISDI would therefore favour the deletion of the table of RNIs in the Annex. In any case, we would suggest the text to be amended as suggested.</p>