

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of
the United Nations



World Health
Organization

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Agenda Item 3

CX/NFSDU 12/34/4

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-fourth Session

Bad Soden am Taunus, Germany

3 – 7 December 2012

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

(Comments at Step 6 of the procedure)

Comments from:

BRAZIL

CHILE

COSTA RICA

GHANA

JAPAN

NEW ZEALAND

PHILIPPINES

UNITED STATES OF AMERICA

GAIN - Global Alliance for Improved Nutrition

IBFAN and IACFO

BRAZIL

GENERAL COMMENTS

In the beginning of this year Brazil presented some comments on the “Draft Nutrient Reference Values” and on the “Draft Revision of the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 8-1991)” in response of CL 2011/24-NFSDU. We do not have new comments on these topics. Thus, we would like to ratify the comments sent previously.

SPECIFIC COMMENTS

6.5 Carbohydrates

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

Brazilian Comments

As proposed before, Brazil thinks that the term “nutritive sweeteners” should be replaced by “sugars as defined in the Codex Alimentarius and/or other carbohydrate sweeteners such as honey”, according to the Codex Committee on Processed Fruits and Vegetables (Alinorm 05/28/27 and CX/PFV 04/22/3).

According to the paragraph 7th 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”.

We consider that the term “nutritive sweeteners” could cause confusion about the real nature about the ingredient, as it can be understood as an additive. The use of additives is set by the item 4.2.2 of the Guidelines.

10.2.4 Instruction for use

10.2.4.8 The label should also include the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk.

Brazilian Comments

Brazil suggests including an item in the section 10.2.4 related to a statement in the labeling regarding the superiority of breastfeeding or breast milk. We think that although these foods are not considered a breast milk substitute, it is important to reassure the importance of breastfeeding. Taking into account that the use of these products must not discourage breastfeeding, we understand that this should be included in the labeling.

ANNEX

TABLE

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

Brazilian Comments

With regard to the table of vitamins and minerals, we think that the values should be based on RNI (Recommended Nutrient Intake), because the document WHO/FAO 2006 doesn't have EAR values for all micronutrients.

CHILE

Background

Chile currently has a national position on this matter, which can be found below:

Document: Draft revision of the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 8-1991)	
Processing status	In processing 5
Purpose:	To provide guidance on nutritional and technical aspects of the production of complementary formulated foods for older infants and young children as defined in Section 3.1, including: <ol style="list-style-type: none"> 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.
Country's position	Chile supports progress to processing 5 of the document entitled "Draft revision of the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children".

Comments:

Following review and commenting by the members of the committee, we continue to maintain the same posture declared previously of supporting continuation of the process, and therefore we have no new comments to make in this respect.

COSTA RICA

Costa Rica would like to express its gratitude for the granted opportunity. However, following a national analysis, it has been decided not to issue any further comments on this topic.

GHANA

Editorial Changes

Ghana suggests the following editorial changes.

1. PURPOSE

Ghana proposes that the phrases ‘Older Infants’ and ‘Young Children’ should begin with upper case throughout the Guidelines for consistency with the various sections:

4.1.2 Legumes and Pulses

4.1.2.1 We propose that soya be changed to soyabeans for consistency with other sections of the document.

4.1.5 Fats and Oils

4.1.5.2 We propose that “Codex STAN 074-1981” be corrected to “CODEX STAN 074-1981, **REV. 1-2006**”.

Rationale: To reflect the current edition of the Standard.

4.2.2 Food additives and flavours

b) last line; We propose that CAC/STAN 192-1995 should be changed to **CODEX** STAN 192-1995.

5.1.2 Dehulling

Separate the words ‘to’ and ‘decrease’ to read ‘to decrease’

5.1.3 Degermination

5.1.3.1, 2nd line

We propose that ‘s’ should be deleted from ‘phytates’ to read ‘phytate’.

5.3 Toasting

5.3.1, 3rd line

We propose that the hyphen between ‘micro’ and ‘organisms’ should be deleted to read “microorganisms” and be consistent with other sections of the Guidelines where it appears.

5.5.1 Extrusion Cooking

5.5.1.1, 2nd line

We propose that the hyphen between ‘extrusion’ and ‘cooking’ should be deleted to ensure consistency with other sections of the Guidelines.

6.2.2, Paragraph 1, line 2

The space between the first bracket and the abbreviation “i.e.” should be deleted.

6.3.2, 1st line

We propose that the numbering of the reference ‘The Protein Digestibility Corrected Amino Acid Score (PDCAAS) ^{7,8,9}’ should be replaced by ^{8,9,10} in the text and the corresponding footnotes.

Rationale: The reference number ‘7’ has been used in both sections 4.1.3.1 and 6.3.2 and has to be changed to ensure correct sequential numbering. Consequently, there should be renumbering of references throughout the document.

6.4.2, 2nd line

The phrase “**Error! Bookmark not defined**” should be deleted.

6.4.3, 2nd line

The acronyms ‘WHO/FAO’ in the sentence should be changed to ‘FAO/WHO’ to read:

“...The levels in the **FAO/WHO**...”, for consistency.

Additionally, we propose the introduction of a reference number ¹³ after the word ‘recommendation’:

“The levels in the FAO/WHO recommendations ¹³”

Also, the corresponding title of the reference should reflect in the footnote accordingly as:

¹³ **FAO/WHO Expert Consultation of Fatty Acids in Human Nutrition, Geneva 2008**

6.4.3, 4th line

We also propose that the texts ‘(FAO/WHO Expert consultation on Fats and fatty acids in human nutrition, Geneva)’ and ‘**Error! Bookmark not defined**’ should be deleted.

Sentence would therefore read:

‘The levels in the FAO/WHO recommendations¹³ may be considered’

6.5.1, 4th line

Ghana proposes that the text in square brackets ‘[If nutritive sweeteners are used, they should be used sparingly]’ should be deleted:

Rationale: Using nutritive sweeteners sparingly is superfluous and does not give much guidance.

6.5.2 Ghana proposes that the footnote for the reference number ¹² now ¹⁴, ‘CAC/GL 2-1885’ is incorrect and should be changed to:

¹² ¹⁴Definition of Dietary fibre given in the Codex Guidelines on Nutrition Labelling (CAC/GL 2-~~1885~~ **1985**)

8 HYGIENE

8.1, 1st line

We propose that “provisions of this standard” be replaced with “provisions of **these Guidelines**”.

Rationale: The document is a guideline and not a standard.

10.2.3, Paragraph 1, 2nd line

We propose that the hyphen between the words ‘Complementary’ and ‘Food’ should be deleted to read:

“...of the Formulated Complementary Food as sold or otherwise distributed”

10.2.4 Instruction for use

We propose that “Instruction” be changed to “Instructions” for consistency with other sections of the document.

10.2.4.6, 4th line

We propose that the word ‘of’ in ‘instruction of use’ should be replaced with ‘for’ to read to read ‘instruction **for** use’ for consistency.

Annex

Ghana prefers the ‘Estimated Average Requirement (100% of EAR) option.

Rationale:

This option gives adequate room for other nutrients that will be obtained from other sources of foods.

JAPAN

Japan supports Draft Revision of the Guideline on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 8-1991).

NEW ZEALAND

New Zealand is supportive of the Committee’s advancement of the draft guidelines for formulated supplementary foods for older infants and young children for adoption at Step 6.

NZ strongly supports the addition of an Annex section to the Guidelines but considers that the Annex section is in need of some direction for its intended use and expert technical input to derive the values

to be included. There is no apparent scientific basis for setting fortification levels at any of the three proposed levels in the table. A recommendation that all nutrients should be fortified at the EAR or RNI (or 70% RNI) does not take into account the risk of adverse health effects associated with excessive intakes. For example, vitamin A has a narrow range of safety between the RNI (400 ug) and UL (600 ug) and fortification at the RNI could place a large proportion of the population at risk of excessive intakes.

The role of the Annex should be to provide guidance on levels of fortification in the absence of locally available nutrient intakes. Depending on the aim of these products this could involve setting minimum fortification levels for vitamins and minerals as is currently in the Guidelines, or to set best-practice fortification levels for the prevention of malnutrition.

Further discussions on the purpose and content of the Annex Table are required to ensure that its use will result in safe and appropriately fortified formulated complementary foods under various local conditions. Further consideration is required on the purpose of the table, selection of values and application of these values.

PHILIPPINES

POSITION

The Philippines appreciates the works of Ghana and the United States for considerable improvements made in the proposed Draft Revision of the Guidelines on Formulated Supplementary Food for Older Infants and Young Children.

The Philippines supports revision of the current Guidelines since nutrition and science have evolved since its adoption in 1991. The revised draft should be based on current scientific evidence reflecting the current dietary patterns of older infants and young children. We are of the view that the revised Guidelines were able to address issues to ensure that complementary foods are nutritionally adequate, safe and appropriate for older infants and young children to meet this group's energy and nutrient needs. We support updating of specific provisions made to description, raw materials and ingredients, nutritional composition and quality factors and labeling.

We support the retention of the bracketed text [If nutritive sweeteners are used, they should be used sparingly.] but with modification to reflect "If nutritive sweeteners are used, they should be used in the lowest amount possible not exceeding 10% of the Energy requirements of infants 6 months and above".

RATIONALE:

Retention of the bracketed text is consistent with the recommendations in The Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases. Limiting the use of free sugar is also in line with The Global Strategy on Diet, Physical Activity and Health endorsed by the World Health Assembly in 2004. Moreover, there is evidence suggesting that increased sweetness in a local supplementary food may stimulate greater intake among older infants (International Journal of Food Science & Nutrition 2001; 52:213-218). We are of the opinion that limiting the amount of sugar in this age group must be balanced against the possible risks of excessive sugar intake, displacement of sugar with more nutrient-rich foods and development of dental caries.

UNITED STATES OF AMERICA

The U.S. supports the Committee's consideration of the text remaining in square brackets at the 34th session of the CCFSDU and advancement of the draft revised guidelines for adoption by the 36th Session of the Commission at Step 8.

GAIN - Global Alliance for Improved Nutrition

We appreciate the opportunity to review the latest proposed draft revision of these guidelines and have a few comments for consideration.

I. GENERAL COMMENTS

Overall, GAIN is in agreement with the majority of the revisions to these Guidelines, as adopted by the 35th Session of Commission. Compared to how they existed prior to revision, the guidelines better reflect the latest scientific evidence on optimal infant and young child nutrition and the range of formulated complementary foods presently consumed by older infants and young children.

II. SPECIFIC COMMENTS

Comment 1: Page 50

6.3.2 The Protein Digestibility Corrected Amino Acid Score (PDCAAS)^{7,8,9} should not be less than 70 per cent of that of the WHO amino acid reference pattern for children from 2 – 5 years .

Comment: It is unclear why the WHO amino acid reference pattern for children from 2-5 years is selected. The WHO amino acid reference pattern for children aged 6 months to 3 years would seem to be more appropriate, as the amino acid requirement per gram protein requirement decreases as children age. For consideration, we present the following wording:

6.3.2 The Protein Digestibility Corrected Amino Acid Score (PDCAAS)^{7,8,9} should not be less than 70 per cent of that of the WHO amino acid reference pattern for children from 6 months – 3 years .

Related to this, in Footnote 7 on the same page, we propose the following for consideration that the denominator of the PDCAAS formula could be changed to:

“mg of limiting amino acid requirement per gram protein requirement for children aged 6 months – 3 years”

Comment 2: Page 54

ANNEX

TABLE

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

Comment: It is unclear why 70% of RNIs are selected as the lower limit. This value seems high, especially when the combination of breastmilk + locally available complementary foods likely provide more than 30% of the RNI for many of the vitamins and minerals listed. We are concerned that with daily consumption of a ration that provides at least 70% RNI, the combination of breastmilk, locally available complementary food, and formulated, fortified complementary food could exceed 100% RNI on a frequent basis. Furthermore, some national regulations (e.g., China’s complementary food supplement standard) set the upper levels for calcium, magnesium, copper and selenium in a daily

ration of complementary food as being <60% of RNI. Thus, the present recommendation of 70% RNI as the lower limit could conflict with some national regulations.

We suggest 50% RNI as a reasonable lower limit. If we estimate that the combination of breastmilk + locally available unfortified complementary foods provides about half the daily vitamin and mineral needs, then consuming a daily ration of formulated complementary foods providing a minimum 50% RNI would provide roughly 100% RNI of the vitamins and minerals listed.

We propose the following for consideration:

The suggested total quantity of each of these vitamins and/or minerals contained in a daily ration of the Formulated Complementary Food is at least 50% of INL₉₈.

Comment 3: Page 52

10. LABELLING

10.1 It is recommended that the labelling of Formulated Complementary Foods for Older Infants and Young Children be in accordance with the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985), the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) and the Guidelines on Nutrition Labelling (CAC/GL 2-1985).

Comment: At the 33rd CCNFSDU Session, GAIN suggested the following wording (in addition to 10.1):

9.2 Nutrient content claims may be permitted provided they comply with nutrition claims and nutrient content claims of the Guidelines for the Use of Nutrition and Health Claims (CAC/GL 23-1997), replacing the Nutrient Reference Values (NRVs) for adults with the FAO/WHO Recommended Nutrient Intakes (RNIs) for infants and young children. Nutrient function claims may be permitted by national authorities for nutrients of specific public health concern in line with supporting national nutrition policy, provided they comply with paragraph 7 of the Guidelines for the Use of Nutrition and Health Claims (CAC/GL 23-1997), replacing NRVs for adults with the FAO/WHO RNIs for infants and young children.

We acknowledge that this language was not adopted at the 33rd CCNFSDU Session. We would like to make the case for why limited nutrition and health claims are critical to promotion of improved complementary feeding and consumption of high quality complementary foods.

Worldwide, there is evidence that nutrient gaps exist in the diets of many children aged 6-23 months, across income levels, and especially among low-income households that rely on a monotonous staple food diet. There is growing acceptance by international bodies, including normative groups such as WHO¹, that micronutrient fortification of complementary foods, either industrially produced or home fortified, holds promise for providing some families with an affordable option to ensure their children get the nutrients they require for healthy growth and development.

GAIN believes that increasing availability of high quality and low cost commercially produced foods, such as fortified complementary foods and complementary food supplements, should therefore be seen

¹ WORLD HEALTH ORGANIZATION, UNITED NATIONS CHILDREN FUND. 2008. Draft meeting report: Strengthening action to improve feeding of infants and young children 6-23 months of age in nutrition and child health programmes. Geneva, 6-9 October 2008.
http://whqlibdoc.who.int/publications/2008/9789241597890_eng.pdf. Date of access: 30 Apr. 2012.

as an important element of any overall strategy to address the nutrient gap during the critical 6 to 23 month period. It is recognized as an important option in both the WHO Global Strategy for Infant and Young Child Feeding² and PAHO's Guiding Principles for Complementary Feeding of the Breastfed Child³.

Not permitting evidence-based nutrition and health claims where warranted will interfere with the right of the public to be informed about the benefits of high quality fortified products specifically designed to meet the nutritional needs of children 6-23 months and to empower them to make choices to provide adequate nutrition for their infants and young children.

In addition, it is of great concern that products not specifically designated for the young child and thus not falling into the "formulated complementary food" category may make nutrient content claims.

Thus, consumers will not be able to distinguish between appropriate high quality fortified complementary foods specifically formulated to fulfill the needs of infants and young children aged 6-23 months, and non-age specific products making nutrient content claims (such as regular breakfast cereals, milk drinks, or even snack foods). The latter may thus appear to offer more health benefits than higher-quality, specially formulated products that are not permitted to communicate this important content information. This could have negative consequences when mothers/caregivers make choices regarding the products they use to complement the traditional foods fed to infants and young children. While potato crisps and chips (which have been reported to be given to young children) can be advertised because they are not aimed (though consumed) by those under 3 years of age⁴, fortified products offering good nutrition cannot under these guidelines in their present form as per WHA Resolution 63.23.

While GAIN fully supports that regulations should stop exaggerated claims and misinformation on foods directed at infants and young children, they should not prevent the transmission of important compositional information that would differentiate complementary foods that have been specifically developed to contain essential micronutrients from low quality products that do not. Without explicit permission for health or nutrition claims, the *Guidelines on Formulated Supplementary Foods for Older Infants and Young Children* (CAC/GL 8-1991), in their present form, will significantly limit efforts by civil society partners to build demand for high quality complementary foods and the scale-up of social marketing aimed at improving access of households to affordable complementary foods and combating micronutrient malnutrition across the globe.

Undoubtedly breastfeeding needs to be protected, and mothers/caregivers also need and have the right to be informed of the content and benefits of appropriate complementary foods, and need to be able to access the foods they need to ensure an adequately nutritious diet for their children. Regulations need to empower and support mothers/caregivers in making informed choices, not disempower them by preventing them from having the information and access necessary to do so. This is consistent with the spirit and objectives of the Codex Alimentarius and the Code of Marketing of Breast Milk Substitutes.

² WORLD HEALTH ORGANIZATION. 2003. Global strategy for infant and young child feeding. http://www.who.int/nutrition/publications/gs_infant_feeding_text_eng.pdf. Date of access: 30 Apr. 2012.

³ PAN AMERICAN HEALTH ORGANIZATION & WORLD HEALTH ORGANIZATION. 2004. Guiding principles for complementary feeding of the breastfed child. http://www.who.int/nutrition/publications/guiding_principles_compfeeding_breastfed.pdf. Date of access: 30 Apr. 2012.

⁴ JONES, S. 2011. Complementary micronutrient supplementation in 6 to 24 month old infants: a focused ethnographic study for GAIN for the purpose of assessing the feasibility of two new nutrient supplements. Report: Final phase. *Unpublished data: Available on request from GAIN.*

Because from 6 months of age adequate and appropriate complementary foods must be added to the child's diet, GAIN believes that the appropriate promotion and distribution of formulated complementary foods must be permitted, and a full range of high quality complementary foods should be encouraged (including local foods and commercially available foods) in a way that supports continued breastfeeding.

Regulations for complementary foods and food supplements should require that products be labeled and promoted in a manner such that they will be used solely as a complementary food and are not misused as a substitute for breastmilk. This will help the public distinguish between products not formulated for this age group (such as regular breakfast cereals, milk drinks, or snack foods) in addition to protecting breastfeeding. In order to avoid possible misrepresentation of the product, certain regulations emanating from the Code need to be established:

- The age of introduction should not precede six months and should be clearly stated on all packaging and in all marketing messages. If pictures are used, children should appear older than six months and show achievement of a physical or developmental milestone clearly reached after six months.
- Instruction should be given to provide a daily ration of the food that is less than the recommended daily energy intake from complementary foods for a breastfed child. Large servings (which are often now recommended for many infant cereals) would interfere with continued breastfeeding and thus act as a breast milk substitute (See table 4.).

Table 4: Energy needs from complementary foods (kcal/day) by feeding status (Pan American Health Organization/World Health Organization 2003).

Age of Child (months)	Energy needs from complementary foods (kcal/day)	
	Breastfed	Not breastfed
6 - 8	200	600
9 - 11	300	700
12 - 23	550	900

- To further ensure that the product is not misused the importance of exclusive breastfeeding for the first six months and continued breastfeeding to two years or beyond should be clearly stated in a conspicuous way on both the product packaging and in all marketing messages.

The *Guidelines on Formulated Supplementary Foods for Older Infants and Young Children* (CAC/GL 8-1991), in their present form, achieve the points above emanating from the Code.

In addition, the regulations should allow companies making complementary foods and complementary food supplements to inform mothers/caregivers as to the nutritional content of their products in order to ensure the sale and promotion of high quality complementary foods for children aged 6-23 months. National regulations or guidelines should however provide guidance to the food industry as to what constitutes evidence-based, acceptable nutrition and health claims for such products in order to prevent abuse and allow responsible promotion towards attaining optimal infant nutritional status through appropriate feeding practices and choices.

IBFAN and IACFO

In line with our previous comments we propose that all food products, including formulated complementary foods intended for older infants and young children should be accommodated under one standard, the Standard for cereal-based foods for infants and young children

((CODEX STAN 074-1982. Rev. 1-2006). A global standard to protect the nutritional health of this vulnerable population for optimal health, growth and development rather than mere guidelines is needed. Simple modifications to the standard, (as was done for the Infant Formula standard) will streamline the legislation and monitoring of these products and ensure that the overarching safeguards cover all the products. This can be done with minor changes such as a change in title, adjustment of footnotes and relevant annexes.

The following items propose how all products can be accommodated into one standard:

Title:

Standard for formulated complementary foods for older infants and young children.

All references to “cereal-based food” in the Standard can readily be changed to all complementary food products..

Scope:

This standard covers all processed foods intended for feeding infants as a complementary food from the age of six months onwards,...

The Scope of the Guidelines defines formulated complementary foods to include “porridges containing cereals”, “ready-to-use products” and “food-based home fortificants” and notes that “processed cereal-based” foods are not covered by the proposed revision of the Guidelines.

Without appropriate definitions of these products, no details are provided to differentiate, for example “porridges”* from “cereal-based” food products. Detailed definitions are required to differentiate these various products. Without clear definitions there will be confusion in how quality standards are applied; how labeling provisions apply and to the use of a specific product. How do the nutritional, hygienic and microbiological quality, the labeling and the use of a “porridge” differ from that of a “cereal-based food”? Clearly a standard that includes all these variations is needed.

* *The dictionary defines porridge as, “is a dish made by boiling oats or other cereal meals in water, milk, or both. It is usually served hot in a bowl or dish. Other grains or legumes may be used”.*

The Wikipedia notes that in many countries, a variety of grains are used to make porridge – rice, wheat, maize, sorghum with additions such as peas, legumes, coconut, nuts, seeds, vegetables, potatoes, eggs, fish, seafood, chicken, meat etc...

Description:

The description of the products under the scope of these guidelines proposes to provide energy and nutrients to “*complement family foods derived from the local diet by providing those nutrients which are either lacking or are present in insufficient quantities*”.

No criteria are provided as to how this is determined. The assessment of the adequacy of dietary intakes of older infants and young children (from 6 to 24 months) is beyond the scope of these guidelines, hence this is not a credible basis on which to support these guidelines.

Additionally the guidelines are not in conformity with the definition of complementary feeding as defined by the WHO in footnote3. Item 3.4 notes the Complementary feeding period, and the definition of a young child. Since the WHO recommended complementary feeding period is to 24 months, this should be stated explicitly in the text rather be left to a footnote. These recommendations are based on best feeding practices and are critical to achieve optimal nutritional, growth, developmental and health outcomes for young children. Extended use of complementary feeding products beyond the recommended duration can exacerbate the risk of obesity and related NCDs.

The Guidelines provide no product definitions, whereas the Standard does include product definitions. The product definitions in the Standard can be expanded to accommodate all complementary food products.

Suitable Raw Materials and Ingredients:

As proposed under the guidelines for formulated complementary foods the ingredients listed do not differ from the ingredients permitted under the Standard for Cereal-based Foods (CODEX STAN 074-1982. Rev. 1-2006):

As proposed under the guidelines for formulated complementary foods the ingredients listed do not differ from the ingredients permitted under the Standard for Cereal-based Foods (CODEX STAN 074-1982. Rev. 1-2006):

...prepared primarily from one or more milled cereal products, such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat. They may also contain legumes (pulses), starchy roots (such as arrow root, yam or cassava) or starchy stems or oil seeds in smaller proportions.

And under Optional Ingredients:

... ..in addition to the ingredients listed under 3.1, other ingredients suitable for infants who are more than six months of age and for young children can be used.

These are the very ingredients proposed as suitable raw materials and ingredients under the Guidelines.

Information on processing to reduce anti-nutritional factors such as phytates, lectins and various inhibitors and be included in an Annex to the CODEX STAN 074-1981 Rev. 1-2006.

Additionally the Guidelines propose the use of defatted oil seeds. Such products are not suitable as foods for infants and young children (Source: UNCTAD secretariat, drawing upon "*Etude relative au mécanisme de formation des prix de cession du coton-graine et des intrants agricoles au Bénin*" (Anna Croles-Rees and Bio Goura Soulé Lares, 2001))

Nutritional Composition and Quality Factors:

The information provided in the guidelines is general and not specific. Energy, carbohydrate, protein and fat requirements are not quantified as they are in the Guidelines. The Guidelines have no limits on sugars – only a suggestion they be used sparingly!; no micronutrient upper and lower limits are set; there no requirements for consistency and particle size; and there are no specific prohibitions such as trans-fatty acids, GMOs, or ionization radiation in the Guidelines to protect this vulnerable population.

These key provisions are provided for in the Standard.

Food Additives:

There are no provisions in the Guidelines for the use and limitation of food additives. This is extensively dealt with in the Standard to ensure that the use of chemical additives are limited and within the recommendations for use.

Lastly, IBFAN continues to be concerned that the proposed Guidelines will increase the burden of the need for regulation of yet another category of products for infants and young children; the monitoring of marketing practices; the 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”.

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, 2007.

Hence the inclusion of all complementary food products under the Standard (CODEX STAN 074-1981 Rev. 1-2006) can facilitate both regulatory needs and safety and nutritional needs. Additionally a standard is more binding than mere guidelines. Foods for older infants and young children need

rigorous and enforceable standards to protect against improper and needless use, chemical contaminants, inferior quality, microbiological contamination and inappropriate marketing and misleading labelling.

IBFAN is also concerned about the impact on consumer decision-making and that these guidelines in addition to the Standard for cereal-based foods will create product confusion in the market place and result in parental misunderstanding of good infant and young child nutrition and optimal complementary feeding. Additionally the enlarged number of products available can increase reliance on commercial products especially in parts of world where resources are scarce. Product reliance also affects taste palettes, and contributes 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. Parents will not be able to differentiate between products marketed under the proposed guidelines and those falling under the current standard for cereal-based foods.

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 24 months reduces the risk of breastmilk replacement.

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 all marketing and labeling of these products are controlled and that recommended 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). Guidelines have less authority to enforce labeling and marketing standards.

WHA Resolution 63.23 (2010) urged Member States (4) to end inappropriate promotion of food for infants and young children and to ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for, in relevant Codex Alimentarius standards or national legislation;

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 optimal growth and developmental is achieved by fortified commercial complementary food products. The proposed draft guidelines assume that local family foods are nutritionally insufficient. Yet the majority of children grow and develop well on breastmilk, complemented with a diet of diverse local family foods after six months of age. The etiology of malnutrition is complex. Until such research is available and clearly confirms an efficacy of these foods with no unintended and unacceptable consequences, older infants and young children should not be subject to mass feeding trials, which displace nutrient rich local family foods and may decrease breastmilk intakes.

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.

Black R E et al. Maternal and Child undernutrition. Global and regional exposures and health consequences. *Lancet* 2008; 371: 243-60

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

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.

Moreover the use of fortified processed foods is not without risk. Needless intakes of excess nutrients have been shown to have detrimental effects. Such an impact may be amplified when infants and young children are sub-optimally or malnourished. Researchers note that much more study is needed to determine the safety of fortified foods compared to family food based complementary feeding combined with treatment of malaria, parasites, diarrheal disease and nutrition education. Domellof notes that “More studies are urgently needed to better determine the risks and benefits of iron supplementation and iron-fortified foods given to iron-deficient and iron-sufficient children”.

Domellof M, *Benefits and harms of iron supplementation in iron-deficient and iron sufficient children*. Nestle Nutr Workshop Ser Pediatr Program 2010; 65: 153-62

A meta analysis (Gera, T et al.) determined that, “therapeutic nutrition products like RUTF for home based management of uncomplicated SAM appears to be safe and efficacious. *However, most of the evidence on this promising strategy has emerged from observational studies conducted in emergency settings in Africa*. There is need to generate more robust evidence, design similar products locally and establish their efficacy and cost-effectiveness in a ‘non-emergency’ setting, particularly in the Indian context”.

Gera T. *Efficacy and safety of therapeutic nutrition products for home based therapeutic nutrition for severe acute malnutrition systematic review*. *Indian Pediatr*. 2010 Aug;47(8):709-18.

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. 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 or obesity. This is not just a result of exclusive breastfeeding up to 6 months, but the fact that breastmilk can provide about one-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.

Dewey. KG. *Nutrition, Growth, and Complementary Feeding of the Breastfed Infant*. *Pediatric Clinics of N.American*. Feb 2001;48(1)